



MSU Graduate Theses

Summer 2020


Psychometric Analysis of a 9-Item M-Hooked-On Nicotine Checklist for Vaping Among College Students

Joshua B. Devine

Missouri State University, Devine23@live.missouristate.edu

As with any intellectual project, the content and views expressed in this thesis may be considered objectionable by some readers. However, this student-scholar's work has been judged to have academic value by the student's thesis committee members trained in the discipline. The content and views expressed in this thesis are those of the student-scholar and are not endorsed by Missouri State University, its Graduate College, or its employees.

Follow this and additional works at: <https://bearworks.missouristate.edu/theses>

 Part of the [Kinesiology Commons](#), and the [Medicine and Health Sciences Commons](#)

Recommended Citation

Devine, Joshua B., "Psychometric Analysis of a 9-Item M-Hooked-On Nicotine Checklist for Vaping Among College Students" (2020). *MSU Graduate Theses*. 3525.
<https://bearworks.missouristate.edu/theses/3525>

This article or document was made available through BearWorks, the institutional repository of Missouri State University. The work contained in it may be protected by copyright and require permission of the copyright holder for reuse or redistribution.

For more information, please contact BearWorks@library.missouristate.edu.

**PSYCHOMETRIC ANALYSIS OF A 9-ITEM M-HOOKED-ON NICOTINE
CHECKLIST FOR VAPING AMONG COLLEGE STUDENTS**

A Master's Thesis

Presented to

The Graduate College of
Missouri State University

In Partial Fulfillment

Of the Requirements for the Degree

Master of Science, Health Promotion and Wellness Management

By

Joshua Bradley Devine

August 2020

Copyright 2020 by Joshua Bradley Devine

PSYCHOMETRIC ANALYSIS OF A 9-ITEM M-HOOKED-ON NICOTINE CHECKLIST FOR VAPING AMONG COLLEGE STUDENTS

Health and Human Services

Missouri State University, August 2020

Master of Science

Joshua Bradley Devine

ABSTRACT

Background: Adolescent participation in electronic vapor products (EVP) is on the rise and with it many new health concerns present themselves. EVP use tripled among high school and middle school students from 2013-2014 and has continued to grow. Previous nicotine related studies have shown that the earlier the age of initiation to nicotine, the higher likelihood to develop a nicotine dependence. **Methods:** Using the “Hooked on Nicotine Checklist” (HONC) current rates of nicotine dependence among college students at a southwest Missouri university was assessed. One hundred and fifty-six students were recruited from a KIN 210 class as a convenience sample. Data was obtained by administering an online survey that was given during the KIN 210 class. **Analysis:** Scores were classified as signs of diminishing autonomy (HONC 1-4) or full autonomy (HONC 0) for each question. Psychometric analyses were run to determine the reliability and validity of the 9-item m-HONC. Descriptive statistics were used to determine the frequency of nicotine dependency, strength of dependency, and the loss of autonomy. **Results:** The 9-item m-HONC reported excellent internal consistency with Cronbach’s $\alpha = .953$, an exploratory factor analysis was also run to confirm the unidimensional nature of the scale.

KEYWORDS: electronic vapor products, vaping, electronic nicotine delivery system, ends, e-cigarettes, smoking, addiction, nicotine, HONC

**PSYCHOMETRIC ANALYSIS OF A 9-ITEM M-HOOKED ON NICOTINE
CHECKLIST FOR VAPING AMONG COLLEGE STUDENTS**

By

Joshua Bradley Devine

A Master's Thesis
Submitted to the Graduate College
Of Missouri State University
In Partial Fulfillment of the Requirements
For the Degree of Master of Science, Health Promotion and Wellness Management

August 2020

Approved:

Melinda Novik, Ph.D., Thesis Committee Chair

Stacy Goddard, DHEd., Committee Member

Riley Galloway, PH.D., Committee Member

Julie Masterson, Ph.D., Dean of the Graduate College

In the interest of academic freedom and the principle of free speech, approval of this thesis indicates the format is acceptable and meets the academic criteria for the discipline as determined by the faculty that constitute the thesis committee. The content and views expressed in this thesis are those of the student-scholar and are not endorsed by Missouri State University, its Graduate College, or its employees.

ACKNOWLEDGEMENTS

I would like to thank the following people for their support during my graduate studies. Dr. Melinda Novik, who served as my chair, mentor, and advisor. Dr. Stacy Goddard, who worked as a committee member, mentor, and content member of my thesis. Dr. Riley Galloway, who worked as a committee member and mentor during my undergraduate program. These three mentors have guided me throughout my studies, and I have enjoyed working with them.

TABLE OF CONTENTS

Introduction	Page 1
Health Problem	Page 1
Research Questions & Hypotheses	Page 3
Delimitations & Assumptions	Page 4
Key Variables & Operationalized Definitions	Page 5
Significance of the Study	Page 5
Literature Review	Page 6
Vaping and Youth Prevalence	Page 6
Nicotine Dependency	Page 9
Non-Nicotine Related Health Concerns	Page 11
Influencing Factors	Page 12
Hooked-On Nicotine Checklist	Page 14
Methods	Page 16
Participants	Page 16
Sampling Procedures	Page 16
Survey Measures	Page 17
Statistical Analysis	Page 18
Results	Page 19
Sample	Page 19
Reliability and Validity	Page 19
m-HONC	Page 21
Frequency of Use	Page 22
Age of Initiation	Page 23
Additional Results	Page 24
Discussion	Page 26
Limitations	Page 28
Recommendations for Future Research	Page 29
References	Page 30
Appendices	Page 36
Appendix A. IRB Approval Certificate	Page 36
Appendix B. m-Hooked-On Nicotine Checklist (m-HONC)	Page 137

LIST OF TABLES

Table 1. Grade and Sex of Users (Use \geq 1 day)	Page 20
Table 2. Cronbach's Alpha Coefficient (m-HONC)	Page 21
Table 3. m-HONC Factor Loadings	Page 21
Table 4. m-HONC Summed Scale Score	Page 22
Table 5. Means for Modified Hooked-On Nicotine Checklist (m-HONC)	Page 22
Table 6. Frequency of Use (Last 30 Days)	Page 23
Table 7. Ever Vaped (Even Just a Puff)	Page 23
Table 8. Age of Initiation (Vape)	Page 24
Table 9. Age of Initiation (Smoke)	Page 24
Table 10. Nicotine Content of Vape	Page 25
Table 11. Frequency of Quit Attempt	Page 25

INTRODUCTION

Health Problem

Electronic vapor products (EVP) use has been rapidly increasing since 2011 (USDHHS, 2014) and this dramatic expansion of this newer product has brought many new concerns. Advertisements and media attention have deemed vaping as a healthy alternative to smoking. Physicians and tobacco counselors perceive that there are lower risks associated to vaping than smoking, however many do not recommend vaping to their smoking patients as an alternative to smoking (Van Gucht & Baeyens, 2016). When the health risks of tobacco emerged, conventional smoking had become a priority for public health (USDHHS, 2014). According to the Centers for Disease Control and Prevention (CDC) in 1965, around 42.4% of adults smoked cigarettes. After countless tobacco control programs, increase in taxes, policies, and health education the smoking rate in 2017 had been reduced to 14.0% (USDHHS, 2014). Likewise, the rate of high school smokers has decreased from 27.5% in 1991 to 2.1% in 2017 (Johnston et al., 2019). The Surgeon General Report: 50 Years of Progress suggests this is one of the greatest public health successes. While there has been a great decline in cigarette use there has been a larger increase of vaping and EVP use in recent years. According to the Morbidity and Mortality Weekly Report (MMWR) from 2013 to 2014, there was an increase in EVP usage among high school students from 4.5% to 13.4% and an increase of middle school students from 1.1% to 3.9% (Brown University Child and Adolescent Behavior Letter, 2015; Arrazola RA, Singh T, Corey CG, Husten CG, Neff Lj, 2015). In 2019, rates for EVP use in the past 30 days for high school was 28.5%, in middle school students it rose to 10.5% (Cullen et al., 2019). Trends have shown that e-cigarette use surpassed conventional smoking rates (USDHHS, 2016) and recent studies have

shown that even dual use, combination of EVP and conventional cigarettes, has surpassed conventional smoking rates among the youth population (USDHHS, 2016). Originally the e-cigarette was marketed towards smoking cessation, however it still contains nicotine at similar potencies as conventional cigarettes. In terms of the priority youth population, 40% of them have never tried conventional cigarettes and 22% engage in dual use of these products (Cooper et al., 2016), alluding to the marketing of youth.

With the dramatic increase of vaping, research on this revolutionary topic is needed and is high priority. Vaping, while advertised as less harmful than cigarette smoking by many companies, is not harmless. One problem is high school and middle school students believe that EVPs are less harmful than any other forms of tobacco and therefore okay to use (Tsai et al., 2018). The list of health effects of EVP are similar to regular cigarettes, in terms of the common risks of chronic obstructive pulmonary disease, coronary heart disease, cardiovascular disease, and cancers (Goniewicz et al., 2014). According to the CDC (2018), smoking accounts for around 480,000 deaths per year, and is the number one preventable cause of death in the United States. The aerosol produced has its own health effects added to the other list of health risks because of the content of the aerosol, having volatile compounds, cancer-causing chemicals, and containing heavy metal particles (Farsalinos, Voudris, & Poulas, 2015). EVP devices also contain batteries and can cause explosions and fires leading to some very gruesome injuries (USDHHS, 2016). The biggest concern with the EVPs is nicotine and the growing popularity among the youth population. Consumers of EVP are misinformed when it comes to nicotine content because some EVPs have been marketed as containing zero nicotine when in fact they do contain nicotine. The Food and Drug Administration (FDA) in 2016 implemented regulations on the EVP market in hopes of reducing youth vaping (FDA, 2016). While not all EVPs have

nicotine, in them, all JUUL pods do have nicotine content (McKelvey, Baiocchi, & Halpern-Felsher, 2018). JUUL usage accounts for roughly 75% of EVP sales (Bach, 2019) and is the popular choice among the youth population due to its compact design, similar to a USB device flash drive. JUUL is a vaping device, classified as an EVP, that uses nicotine salts to deliver nicotine doses through the aerosol by vaporizing the juice in their “pods.” Nicotine when used before the age of 25 causes harm to adolescent’s brain development (Kota, Martin, & Damaj, 2008). Specifically, it harms the portion of the brain that is responsible for controlling attention, learning, mood, and impulse regulation (USDHHS, 2016). In concern to the attention and cognition aspect that nicotine has, studies are showing a decrease in working memory (Jacobsen et al., 2005). Treur et al., 2015 states in monozygotic twins there was a greater increase in attention problems compared to their non-smoking twin during adolescence and into adulthood. Nicotine also has an effect on the nicotinic acetylcholine receptors and during adolescent years has increased sensitivity to nicotine and strengthens the stimulus reward received (Kota et al., 2008), possibly explaining why many adults who are addicted started prior to the age of 20 (Hyman & Brown, 2012). Due to the novelty of EVP, longitudinal studies for health effects are still needed, for now data from longitudinal smoking research is used to generalize effects.

Research Questions & Hypotheses

One of the research aims of the study is to identify the reliability and validity of using a 9-item m-HONC for college students.

- It is hypothesized that the scale will maintain the original psychometric properties.

Another research aims in this study is to identify the degree of nicotine dependence, through a summed HONC score, for college students.

- Directional: There will be a high degree of nicotine dependence among college student EVP users.
- Non-Directional: There will be nicotine dependence among college student EVP users.
- Null: There will be no degree of nicotine dependence among college student EVP users.

The next research aim is to determine the relationship between EVP frequency of use and the degree of nicotine dependence.

- Directional: There will be an increase in degree of nicotine dependence when EVP frequency of use increases.
- Non-Directional: There is a relationship between EVP frequency of use and the degree of nicotine dependence.
- Null: There is no relationship between EVP frequency of use and the degree of nicotine dependence.

Lastly, the research aims to determine the relationship between age of EVP initiation and the degree of nicotine dependence.

- Directional: There will be an increase in degree of nicotine dependence as age of EVP initiation decreases (younger).
- Non-Directional: There is a relationship between the age of EVP initiation and the degree of nicotine dependence.
- Null: There is no relationship between the age of EVP initiation and the degree of nicotine dependence.

Delimitations & Assumptions

Delimitations and assumptions of the study include the use of the 9-item modified Hooked-on Nicotine Checklist with the college population. The use of Qualtrics to administer an online survey. Participant responses were not affected by other questions in the parent survey. The use of the modified HONC (m-HONC) summed scores for the use with EVP and the modification to the scale to determine degree of dependence. The study is also delimited by the focus on nicotine dependence, frequency of EVP use, and age of EVP initiation.

Key Variables & Operationalized Definitions

- Vaping, for the terms herein, is defined as inhaling and exhaling aerosol vapor, produced by EVP.
- Electronic Vapor Products (EVP) is a collection of electronic devices used with nicotine products. Types of EVP include; “vapes,” “e-cigarettes,” “e-cigs,” “e-hookahs,” “mods,” “tank systems.” Due to the vast amount of designs and appearances of these new devices, this report will refer to them as “EVP”
- Degree of dependence is based on the summed score on the m-HONC, the higher the number the stronger the degree of dependence.
- Age of EVP initiation is determined by first use of Vaping even just a “puff”
- Frequency of EVP use is determined by days used in the last 30 days.

Significance of the Study

The findings of this study provide valuable information on the degree of nicotine dependence among college students within a southwest Missouri college that partake in use of EVP. This study also seeks to examine the relationship between information on age of initiation and frequency of use of EVP and nicotine dependence. This study has brought much needed awareness and attention to the prevalence of nicotine addiction and dependence among college-age young adults caused by vaping. Identifying the reliability and validity of using a modified Hooked-On Nicotine Checklist (m-HONC) scale to identify the degree of dependence. Research in this topic of vaping is in high demand as it is becoming a larger public health concern. EVP use is a trending habit and rapidly becoming a culturally acceptable behavior. The adolescent and young adult population is at an increased risk to developing dependence to these nicotine products and can lead to conventional smoking and even dual-use of the products. Finally, this study is adding to the public knowledge of EVP behaviors and usage patterns among the adolescent population.

LITERATURE REVIEW

Vaping and Youth Prevalence

With the steady decline of conventional cigarette smoking there has been a significant increase in use of new tobacco products, specifically EVP (USDHHS, 2016). These new products have many different designs and sizes, but all have similar uses and produce vapor. EVP use among the younger population is at an all-time high and is now the most common tobacco product used (Hyman & Brown, 2012). The sales of EVP in the United States have grown since 2011 and soared during the 2013-2014 time where regular usage among the youth tripled from 4.5% to 13.4% (Brown University Child and Adolescent Behavior Letter, 2015). The 2018 National Youth Tobacco Survey (NYTS) reported that 27.1% of adolescents have used an EVP in the last 30 days. In middle school students, 13.5% of them have tried and for high school students 37.7% have tried (CDC, 2018). While the Youth Risk Behavior Surveillance Survey (YRBS) in 2017 reported a significantly larger percentage for high school students of 42.2% of adolescents have tried (CDC, 2017). Regardless of the discrepancy between numbers, both are larger than conventional cigarette usage among both populations, where rates of conventional smoking were as low as 7.6% in high school and 2.1% in middle school (CDC, 2017; USDHHS, 2016). According to the Spring 2019 American College Health Assessment – NCHA II 25.5% had ever used EVP and 18.8% of college student had ever used conventional cigarettes. These trends continue into 2019 as conventional smoking decreases, e-cigarette usage increases more. A major concern is the gateway effect (Davis, Kauffman, Singer, Gebremariam, & Clark, 2013; USDHHS, 2016) of e-cigarette use that has bridged a gap to conventional cigarettes, other tobacco products, and even cannabis products (Morean, Kong, Camenga,

Cavallo, & Krishnan-Sarin, 2015). Studies in 2016 by Miech, R. et al. (2016) have reported that 8th graders who start smoking EVP are ten times more likely to smoke conventional cigarettes than their peers who do not. That trend continues into 10th and 12th grade students at a lower rate of eight times and six times, respectively (R. A. Miech, O'Malley, Johnston, & Patrick, 2016; R. Miech, Patrick, O'Malley, & Johnston, 2017). Dual use, most commonly the combination of EVP and conventional cigarette use, is also a major concern with youth and young adults who have been partaking in both behaviors increasing their risk (Demissie, Everett Jones, Clayton, & King, 2017). A survey on adults at the University of Michigan showed that 44% of adults believe e-cigarette use among the youth will eventually lead to the use of conventional tobacco products (Davis et al., 2013). FDA's Deeming Rule, part of the Tobacco Control Act of 2009, has had authority over EVP since 2016, but not until August 2018, the compliance date, did the new policies and regulation on EVP come into effect to combat youth under the age of 18 having the ability to purchase these e-cigarette devices (FDA, 2019). Furthermore, companies had to begin displaying health warnings on their products. Prior to the regulations, anyone with access could purchase these devices and e-liquids online. Popular internet platform, Reddit, contained a discussion board called "UnderageJuul," where users were using this platform to find where they could purchase these JUULs and even pay someone else to purchase it for them (McKelvey, Baiocchi, et al., 2018). This was just one of many backdoor ways for underage EVP users to purchase e-cigarette devices, such as JUUL.

One reason for this large jump in EVP sales is due to the new product JUUL. JUUL was released in June 2015 and took the e-cigarette world by storm and accounting for 68% of the e-cigarette sales in the United States (LaVito, 2018). In 2019, that has increased to 75% of the market share (Bach, 2019). The JUUL has a unique design and is sleek and small, to the unaware

eye it looks like a USB flash drive. The JUUL product is an exception to the vaping rule where not all vapes have nicotine, in the case of JUUL's they always have nicotine ("JUUL," 2019). According to a study of California high schools only 25% of students knew that they always contained nicotine (Willett et al., 2019). Originally, there was only one concentration of nicotine sold, 5% (TruthInitiative, 2019), now they sell 3% and 5%, according to JUUL's website.

A study in the UK surveyed e-cigarette users and the reason they chose to switch to EVP (Measham, O'Brien, & Turnbull, 2016). Several respondents enjoyed the new flavors and the ability to perform tricks, such as cloud chasing. "Cloud Chasing" is a term used for those who perform tricks with the vapor byproduct of EVP. The younger participants in the survey spoke strongly about the various tricks they could do and how you could create effects like the "hoops" and "tornadoes." Tricks were listed second as a reason the youth enjoyed EVP, behind flavors. Flavors like "Sex on the Beach," "Skittles and Red Bull," and flavors with cannabis combinations had youthful elements according to the study by Measham et al. (2016). This study is a clear indicator of the social culture that vaping has already created and how it can be linked to status in the UK.

Marketing of EVP has also been a huge concern when it comes to youth appeal. Studies have shown with increased exposure to advertisements and other nicotine related products the likelihood of initiation of other nicotine products in the youth population increases (Padon, Maloney, & Cappella, 2017). Padon et al. (2017) used a Content Appealing to Youth (CAY) index that categorized 154 EVP advertisements. The CAY index looks at value, appeals, youth themes, reward appeals, and miscellaneous content dimensions inside each of the advertisements. The study found many similar features used previously by the tobacco industry to find youth appeal, through social status, appearance, and celebrity themes. Padon et al. (2016) also suggests

targeting certain brands who focus more on the youth appeal than banning all advertisements as they believe some advertisements are focusing on adult smoking cessation.

Nicotine Dependency

The repeated drug exposure of nicotine leads to nicotine dependency, or addiction. The regulation of EVP has provided consumers with more information on nicotine levels. Prior to this some consumers were unaware of the content (TruthInitiative, 2019; Willett et al., 2019). Even still it is difficult to identify the level of nicotine absorption due to the number of different devices, each burning at a certain level, some research says nicotine dose increases based on the efficiency of the device and turning up the heat increases nicotine absorption (Farsalinos et al., 2015). According to the CDC, 9 out of 10 current conventional cigarette smokers first use was before the age of 18 (USDHHS, 2014), this is a large concern considering the youth population is starting at even earlier ages with EVP. The psychoactive drug (Yuan, Loughlin, & Leslie, 2015), nicotine, has stronger damaging effects on the adolescent brain in comparison to an adult (USDHHS, 2016). As stated above, the earlier the stages of brain development for adolescents is more susceptible to nicotine dependency due to the sensitivity of the nicotinic receptors (Kota et al., 2008). Age of first use is also an important factor because when smoking began at a younger age, the transition from monthly to daily use smoking occurred more rapidly (Dierker, Swendsen, Rose, He, & Merikangas, 2012). EVP can generate comparable nicotine doses to that of conventional smoking, allowing the future nicotine dependency to be compared (Dawkins, Kimber, Doig, Feyerabend, & Corcoran, 2016). According to a study of the youth population, symptoms of nicotine dependence in smoking can be seen even with the low use of 1-3 cigarettes per month (Rose, Dierker, & Donny, 2010). The Surgeon General Report on EVP stated that few

validated measures exist currently to assess nicotine dependence with EVP, many researchers use adapted versions used for conventional smoking surveys, like the HONC or Fagerström. Nicotine also has effects of cancers, cardiovascular diseases, reproductive complications, lung development, cognitive function (USDHHS, 2016). Among these concerns nicotine also has an effect of immune function with suppressive effects depending on nicotine levels. There are many risk factors and protective behaviors that can predict nicotine dependence in adolescence.

A study by Hu, Griesler, Schaffran, & Kandel, 2011, investigated these predictors and found that adolescent nicotine dependence, parental nicotine dependence, pleasant initial sensitivity, and extensiveness of smoking are strong predictors of future nicotine dependence. The strongest factor being pleasant initial sensitivity looking at experiences, sensations at first use, pleasure, and relaxation (Hu, Griesler, Schaffran, & Kandel, 2011)Coop. Age of initiation is another variable that can predict adolescent nicotine dependence as adults who began smoking before the age of 19 had a significantly higher nicotine dependence than those who started at age 25 and above (Park et al., 2004). When looking at school age adolescents 67% of 6th grade who began smoking became regular smokers compared to only 46% of eleventh graders became regular smokers (Lynch & Bonnie, 1994). The initial pleasant feeling that is coming from vaping influences the likelihood of continued use because it is creating positive relationships to be made between the user and the product (Chen et al., 2003). As adolescents who are already at a higher likelihood of building a dependence (Kota et al., 2008) this makes age of initiation important.

Nicotine dependence is influenced by a multitude of factors, including environmental, social, pharmaceutical, and psychological reasons. Inhalation of the drug nicotine is a very efficient process; within seconds the nicotine enters the brain. The nicotine then binds to nicotinic receptors in the brain in which releases neurotransmitters. One of the main

neurotransmitters released during this binding is dopamine. Dopamine is responsible for the pleasure response and is one of the main reinforcing factors to nicotine dependence (Benowitz, 2010). After repeated exposure to the psychoactive drug, nicotine tolerance begins to occur. Tolerance of nicotine happens due to the desensitization of the nicotinic receptors and due to the increase in binding sites on the receptors through neuroadaptation (Benowitz, 2010). Benowitz (2010) said withdrawal of nicotine is another factor that influences nicotine dependence because of the stress and anxiety that caused smokers to use again or deal with the symptoms. Avoidance of withdrawal and positive mood enhancement are both reasons for repeated nicotine use.

Non-Nicotine Related Health Concerns

While nicotine is currently the primary concern for e-cigarette users among the youth, the need for more information about what goes into making EVP is needed. Research on emissions of EVP provides important information on what other products and compounds are in the aerosol that is being smoked. First, aldehydes are emitted into the aerosol during the heating and oxidation process of the e-liquid (Farsalinos et al., 2015). New generation devices found formaldehyde, acetaldehyde, and acrolein are being related at levels that approach and possibly exceed conventional cigarette smoke (Goniewicz et al., 2014). These carbonyl compounds are known irritants, carcinogens, and linked to pulmonary emphysema (Goniewicz et al., 2014). While this phenomenon known as a dry puff is not typical use it does present itself to the higher levels of carcinogens. Flavor chemicals are another concern, with their being over 7,000 different flavors on the market (Zhu et al., 2014), testing each product and the interaction effects would take time. Some researchers are identifying diacetyl in the flavorings of the e-liquids, which is responsible for airway epithelial damage, popcorn lung (Hubbs et al., 2012). Like conventional

cigarettes, toxins in EVP are responsible for the deterioration of endothelial cells, leading to the damage of body's blood vessels, according to the American Heart Association (AHA, 2018). Health effects outside of the inhalation of the aerosol are also common. The batteries inside the e-cigarette devices have been known to explode, deaths have been caused by these explosions and serious harm has occurred during the use of these EVP. Consumption of the nicotine e-liquids has also occurred and caused nicotine poisoning, 51% of poison control centers that dealt with EVP involved a child 5 or younger coming in contact with the nicotine containing e-liquids (USDHHS, 2016).

Influencing Factors

Social culture had a huge impact on smoking rates in the past 50 years. The public health initiatives have effectively denormalized smoking, the reason many people have negative thoughts towards those who smoke. The connection of attitudes towards smoking is a strong indicator of the likelihood to participate. McKelvey, Popova, Pepper, Brewer, & Halpern-Felsher, 2018 showed teens who have a positive image of smoking and vaping have a higher chance to participate in e-cigarette use. This evidence goes along with the social culture vaping has created in the youth as it is seen as “cool” and sociable if you participate. McKelvey et al. (2018) concluded that peer opinions were negative towards those who smoked describing them with unattractive traits like “trashy”, “immature”, and “disgusting.” Where students who did participate in e-cigarette use described themselves and others positively, with “cool”, “sociable”, and “sexy.” Those who identified with those positive views were twice as likely to begin using EVP than those who viewed it as negative. A study of Texas youth identified social norms and factors of different types of tobacco use including EVP (Cooper et al., 2016). This study found

that there were significant differences in social factors between the different types of tobacco products. Students were more likely to date someone who uses an e-cigarette compared to any other tobacco product, students were more likely to be okay with friends who used EVP alone compared to any other product. Peers also identified EVP as more common than all the other tobacco products. The same study looked at risk perceptions and, with no surprise, users of EVP did not believe they were harmful, or could be addictive (Cooper et al., 2016). Cooper et al. (2016) concluded that the more exposure and lower perceived risks the higher likelihood of youth initiation. Exposure to advertisements relating to EVP was gathered by Nielsen, a company that provides television advertising data. The Nielsen Monitoring system tracks information on a large amount of US network television and evaluates distribution of advertising by brand. Results showed that blu eCigs accounted for 81.7% of the marketing towards youth (12-17) and account for 80.4% of brand advertisements towards young adults (18-24) in 2012 (Duke et al., 2014). Current advertising of these EVP brands includes celebrities and film stars using. Previous evidence has shown that there is an association between smoking in film and smoking initiation in youth (Duke et al., 2014). These advertisements can create new social norms and increase the likelihood of youth initiation to EVP. The rapidly evolving market for EVP could be due to the increase in media campaigns in advertising for the use of EVP.

In 2015 a study by Rebeca Williams was published in the Journal of Public Health Policy describing Vaping conventions. These conventions have raised concern due to the growing popularity and frequency and how these conventions are playing a role in the growth of the EVP community. EVP companies are using these conventions as methods of promotion for their products and have reinforced the social norm around EVP. The exposure of these conventions allows participants an avenue to include friends and create a larger social event (Williams, 2015).

Williams (2015) identified 41 different organizations in the vaping community totaling over 90 conventions and 37 locations around the US and internationally since 2010. The US totaled for 82.9% of the organizations leaving only seven internationally. Vendors and sponsors attended these Vaping conventions and sold products allowing participants unregulated access to new products. Proceeds from admission prices, sales, and donations from retailers, which exceeded \$100,000, funded research for the National Vapers Club, who published on the safety of EVP vapor in 2012 (McAuley, Hopke, Zhao, & Babaian, 2012). A search on Google in 2019 of “Vaping Conventions” listed a website ECigIntelligence, this website listed 48 events between the US and International conventions. The website also mentioned that they do not list all the vaping events, this was alarming due to the sharp increase from roughly 18 a year, according to Williams (2015), to 48 just in one year. Apart from the advertisements and marketing stunt that these expos allowed, another health concern is related to the secondhand smoking policy and indoor smoking policies. In 2014 the “Electronic Cigarette Convention Expo had 18,000 attendees and set the world record for number of vapers vaping inside one building (Williams, 2015). Individuals who attend these conventions are at a high risk to exposure to secondhand vapor, vapor filled rooms are filled with hundreds sometimes thousands of people and create a list of potential hazards.

Hooked on Nicotine Checklist (HONC)

Nicotine dependence has been measured commonly by two instruments the Fagerström and the Hooked-on Nicotine Checklist (HONC). The Fagerström Test of Nicotine Dependence (FTND) has lower psychometric properties when compared to the HONC (R. Wellman et al., 2005). Wellman et al. (2005) tested validity of the FTND and found that it correlated more with

cigarette consumption than the intended prime variable of nicotine dependency. The Hooked-on Nicotine Checklist (HONC) is a reliable and valid measure of nicotine dependency by identifying diminished autonomy through a ten-item checklist. The HONC has been a useful tool in measuring the nicotine dependency among smokers, from heavy smokers to light smokers (DiFranza et al., 2002; Wellman et al., 2005). The strength of the HONC among the spectrum of smoking habits allows for an easier application to the population of adolescents as many of them are not long-term users of nicotine. Usage of the HONC for nicotine dependency has many benefits. First, all the items on the HONC have face validity for diminished autonomy, which is a key concept in the sensitization-homeostasis theory model of nicotine dependence (Wellman et al., 2005). The sensitization-homeostasis theory states that nicotine has the ability to bypass the autonomous support craving circuit, creating withdrawal-induced cravings after the effect of nicotine wears off (DiFranza, Huang, & King, 2012). In a study of 215 adolescents, the HONC survey had significant internal consistency ($\alpha=0.92$) (Wellman et al., 2005). Wellman et al., (2005) also measured intraclass correlation for HONC over 6-month and 12-month follow ups, alpha levels of .93, .91, respectively were found. The has gone through reliability studies with one-week and two-week kappa values of .61 and .76 respectively. Internal consistency tests reported the HONC to have a Cronbach's alpha level of .91. The HONC has been adapted to incorporate questions pertaining to EVP, Bonnie Halpern-Felsher (2018), in a study of 445 adolescents, modified the HONC for use with adolescents and EVP (McKelvey, Baiocchi, et al., 2018). The strong reliability and validity of the HONC, compared to other methods of measuring nicotine dependence, target population of adolescents, and adaptation for EVP has made this a strong case for use in this study.

METHODS

This study was approved by the Institutional Review Board on November 8th, 2019 (IRB-FY2019-345) (Appendix A).

Participants

The target population of this study is young adults, specifically students enrolled in KIN 210: Healthy Lifestyles: Preventative Approaches at Missouri State University. KIN 210 is a general education class and is geared towards assisting university students in understanding values of health and physical fitness. The data in this study was provided by 11 KIN 210 Lab sections. The population offers 191 prospective students with varying majors, educational levels, and sex. The population of young adults at Missouri State University are predominantly White (80.0%), African American (3.7%), and Hispanic (3.1%) with varying socioeconomic statuses, according to the Missouri State University 2018-2019 FactBook, available online.

Sampling Procedures

Convenience sampling was used as access to these classes was available through relationship with class coordinator. The survey was conducted during the time of October-November 2019. Informed consents were a part of the survey and students could choose to not take the survey. Upon agreeing to the informed consents, the survey was administered to the students via online survey. Those who agreed to complete the study comprised the sample for analysis. The survey was de-identified and then downloaded into an Excel spreadsheet to be uploaded to SPSS for analysis. The parent survey would not have any exclusion criteria;

however, participants were excluded from taking the HONC if they answered “No” to the question, “Have you ever vaped, even just a puff.”

Survey Measures

The m-HONC measure (Appendix B) includes the following questions to determine strength of dependence. “Have you ever tried to quit?” “Do you use because it is hard to quit?” “Have you ever felt like you were addicted?” “Cravings towards?” “Is it hard to keep from using during school?” These are a few of the items that are listed on the HONC. The HONC is a 10-item instrument identifying the strength of dependence among adolescents and their smoking (DiFranza et al., 2002). Question one was removed from the scoring as it is a yes or no question asking about if they had ever attempted to quit and scaling the option would not make sense. The HONC was adapted for use with EVP in a study of California high school students to determine nicotine dependence (McKelvey, Baiocchi, et al., 2018). The HONC has been further modified, with permission from author, in this study to include scale responses of 0-4 (0- Not at All, 1 – Slightly, 2 – Moderately, 3 – Very, 4 – Extremely), to look deeper into the strength or degree of dependency. Autonomy is lowered as the respondent’s scores increase with a maximum score being 36 representing full loss of autonomy, and a score of 0 representing full autonomy. The degree of dependence, the key variable, is also reflected by the higher summed score of all the items. A score of 0 would indicate the respondent had full autonomy, a score of 1-9 would indicate a mild degree of dependence of nicotine, a score of 10-26 would be considered a moderate degree of nicotine dependence, a score of 27-35 would be considered a high degree of nicotine dependence, and finally a score of 36 would indicate a full loss of autonomy. The

adaptation of the survey does not change the target of nicotine dependence, but only describes the use of EVP rather than conventional smoking.

The m-HONC measure was part in a parent survey that included questions identifying perceptions, frequency, prevalence of EVP use, and demographics among the youth population. Age of EVP initiation was identified in the survey by asking participants to recall their age when they first used an electronic vapor product, even if it was just a “puff.” A puff is defined as one inhalation on the EVP, regardless of nicotine level. Frequency of EVP use was determined using a question asking about how many days in the last 30 days did the participant use an electronic vapor product. The parent survey also provided some demographical information such as grade and sex.

Statistical Analysis

Analysis of the m-HONC summed scores were performed using SPSS version 24. Psychometric analysis was used to determine the reliability and validity of the modified HONC, due to the modification of response answers and questions for the use with EVP using a factor analysis and a Cronbach’s alpha score. Descriptive statistics were used to determine EVP dependency, age of initiation, and frequency of use. Bivariate correlations were run to examine the relationships between EVP dependency, age of initiation, and frequency of use. Finally, a multiple linear regression was used to determine the strength of relationship between age of initiation and frequency of use on dependency, while controlling for demographic variables.

RESULTS

The primary purpose of this study was to examine the reliability and validity of the m-HONC, through factor analysis and descriptive analysis of the scale questions. Further examinations tested the relationships between the variables of age of initiation and frequency of use and their effect on degree of nicotine dependence among the population.

Sample

For the study, 191 students were recruited to participate from a general education class over two days during the KIN 210 lab class session. A total of 154 students chose to participate in the survey. The sample was comprised of 53.2% females and 37.7% males, 14 (9.1%) participants chose not to answer. This falls in line with the university demographics according to Missouri State Universities 2018 Diversity Report with females comprising of 59% of the university. Frequency of use across grade and sex are found in Table 1.

Table 1. Grade and Sex of Users (Use \geq 1 day)

	Freshmen	Sophomore	Junior	Senior	Total (n)
Male	1	6	13	2	22
Female	6	23	10	3	42
Total (n)	7	29	23	5	64

Reliability and Validity

Beginning with the psychometrics of the 9-item m-HONC, results found that the new measure had high internal consistency yielding a Cronbach's alpha score of $\alpha = 0.953$ (Table 2). The decision to eliminate the first question on the HONC (If you have ever tried to quit, how

hard was it to quit Vaping?) was made because the question was not answered by many of the participants due to having not tried to quit and skipping the question. The remaining 9-items were used for the psychometric testing and factor analysis (Table 3). The factor analysis of the m-HONC provided further confirmation on the unidimensional measure and after running a KMO and Bartlett's Test it showed there was adequate sampling (KMO = 0.819). The unidimensional factor was robust with an eigenvalue of 6.603, accounting for 73.36% of the total variance.

Table 2. Cronbach's Alpha Coefficient (m-HONC)

Cronbach's Alpha	N of Items	N
.953	9	39

Table 3. m-HONC Factor Loadings

m-HONC Questions	Loading
How likely are you to continue to vape because it is too hard to quit?	0.724
How addicted do you feel to vaping?	0.864
How strong are your cravings to vape?	0.844
How strongly do you feel you really need to vape?	0.892
How hard is to keep from vaping in places where you are not supposed to, like school?	0.842
How hard was it to concentrate because you could not vape?	0.809
How irritable did you feel because you could not vape?	0.902
How strong of a need did you have to vape?	0.920
How nervous, restless or anxious did you feel because you could not vape?	0.895

m-HONC

As a secondary objective, summed scores were calculated from the 9-items, and then descriptive statistics were run for each individual scale questions. The m-HONC summed score (Table 4) showed an average score of 9.95 (9.03) (n= 39). The minimum score was 0 out of 36 and the maximum score was a 33 out of 36. The scores from the individual questions varied with the lowest average score being how hard it is to concentrate when you could not vape. The score with highest average was the question pertaining to the cravings towards vaping (Table 5).

Table 4. m-HONC Summed Scale Score

Mean	9.95 (9.03)
Min	0
Max	33
N=39	

Table 5. Means for Modified Hooked-On Nicotine Checklist (m-HONC)

m-HONC Questions	Score
How likely are you to continue to vape because it is too hard to quit?	1.26 (1.25)
How addicted do you feel to vaping?	1.49 (1.19)
How strong are your cravings to vape?	1.64 (1.14)
How strongly do you feel you really need to vape?	1.15 (1.18)
How hard is to keep from vaping in places where you are not supposed to, like school?	0.77 (1.14)
How hard was it to concentrate because you could not vape?	0.72 (1.17)
How irritable did you feel because you could not vape?	0.95 (1.17)
How strong of a need did you have to vape?	1.15 (1.27)
How nervous, restless or anxious did you feel because you could not vape?	0.82 (1.07)
m-HONC Summed Score	9.95 (9.03)

Frequency of Use

Frequency of use was analyzed. Respondents answered a question pertaining to how many days they vaped in the last 30 days and averaged 7.24 (11.18) days (Table 6). Many of the respondents (n=52) answered zero of the days indicating that they have not vaped in the last month, but had vaped before, at least a puff (n=101) (Table 7). American College Health Association – National College Health Assessment (ACHA-NCHA II) in Spring 2019 reported that 70% had never used e-cigarettes (Question 8A10). In this sample it was found that only 34.4% had never vaped (n=154). It was also found that 9.1% were considered daily users, having responded to vaping 30 out of the last 30 days, when compared to the ACHA-NCHA II at 6% (ACHA, 2019). Frequency of use was also analyzed with grade level and sex. Finally, a Pearson's Correlation was used to assess vaping use in the last 30 days and the m-HONC and showed statistical significance, $r(37) = .440, p < .01$, with a positive correlation.

Table 6. Frequency of Use (Last 30 Days)

Mean	7.24
Std. Deviation	11.18
Minimum	0
Maximum	30
Total (N)	97

Table 7. Ever Vaped (Even Just a Puff)

	Count	%
Yes	101	65.6
No	53	34.4
Total (N)	154	

Age of Initiation

Age of initiation was another important variable and participants were asked “How old were you when you first vaped (even just a puff)?” in addition to a similar question pertaining to conventional cigarettes. Age of initiation for vaping was 17.13 (1.64) (n=101) (Table 8), for conventional cigarettes 16.76 (1.73) (n=54) (Table 9). Thirteen was the youngest age for both questions. Further examination of the variable looked for correlation between Age of Initiation of vaping and the m-HONC summed score. Age of Initiation of vaping and the m-HONC had a weak, non-significant, negative correlation $r(37) = .098$, $p = .552$.

Table 8. Age of Initiation (Vape)

Age	Count	%
13	1	1.0
14	4	4.0
15	8	7.9
16	22	21.8
17	28	27.7
18	22	21.8
19	8	7.9
20	4	4.0
21	3	3.0
22	1	1.0
Total (n)	101	17.13 (1.64)

Table 9. Age of Initiation (Smoke)

Age	Count	%
13	2	3.7
14	3	5.6
15	6	11.1
16	14	25.9
17	10	18.5
18	13	24.1
19	2	3.7
20	3	5.6
21	1	1.9
Total (n)	54	16.76 (1.73)

Additional Results

Analyses on perceptions of nicotine content were also included and could provide interesting information. Table 10 indicates the knowledge about the nicotine content of the vapes and only 59% of the users, who indicated they had ever used, said they knew the vape they used had nicotine in it. According to a CDC study (2019) 99% of all vapes have nicotine in them, even when labeled as nicotine free. Table 11 indicates individuals who attempted to quit vaping based on the first question of the m-HONC, those who answered the question at all were considered to have a quit attempt.

Table 10. Nicotine Content of Vape

	Count	%
Yes	59	59.0
No	26	26.0
Unsure	15	15.0
Total (n)	100	100%

Table 11. Frequency of Quit Attempt

	Count	%
Yes	55	55.6
No	44	44.4
Total (n)	99	

DISCUSSION

To the researcher's knowledge this is the first study to look at strength of nicotine dependence among college EVP users using the m-HONC scale. Dealing with a new and developing epidemic of vaping has proven to be hard as emerging data is coming out monthly. New coverage in the media has increased awareness among all populations and creates issues with individuals receiving false information or using outdated information. Due to the deaths that have been caused by vaping there has been a large push back towards vaping companies and changing perceptions of adults and students who use, even those who do not use. The public health concern surrounding vaping has grown rapidly and exhibits a clear need for focus.

The first aim was to look at the m-Hooked-On Nicotine Checklist (m-HONC) and modify the measure to be able to look at the strength of dependence through a scale rather than a nominal scale. The literature suggested that the HONC could be modified to look at the degree of dependence (or degree of loss of autonomy) (Wellman et al., 2005). Using a scale of 0-4 allowed for a logical cut off score of 0, showing no signs of dependence, all the way to 36, which is a high strength of dependence. Psychometric testing was done on the 9-item m-HONC measure and proved to be an effective measure for assessing strength of nicotine dependence among the young adult population. This result was expected according to a previous study looking at the psychometric properties for the HONC showing similar results (Wellman et al., 2005). Wellman et al. (2005) showed a Cronbach's $\alpha = 0.94$, whereas the current study showed an increased α score of 0.953 (Table 2). The results of the psychometric testing confirm that the change to the HONC did not reduce its strong reliability and validity.

The secondary purpose of this study was to examine the m-HONC summed scores to look for degree of nicotine dependence among college student EVP users. The summed scores that were calculated were lower and many of the participants who had ever vaped reported low levels of dependency. The initial thought was because it included those who had not vaped at least once in the last 30 days in the statistical analysis. Logically, there should be low levels of dependence among those who have not vaped in the last 30 days. The correlation between use in the last 30 days and the dependency summed score confirmed the hypothesis of increased days of use increased their reported dependency. Questions on the HONC that show low scores can provide useful information and be interpreted in different ways. The question asking participants about “How hard is it to keep from vaping in places where you are not supposed to, like school?” shows that participants may perceive it as easy to use in places where they are not supposed to because they can get away with it. They may know that it is wrong, but because it is easy to get away with, perceive it as not difficult at all. We see most of our lower dependency scores coming from the final questions on the scale, pertaining to when participants were not able to vape, indicating that they may not have to go without for long periods of time because they are able to use whenever they need. Finally, question 1 provided information about how many of the participants had attempted to quit (Table 11). This number is surprisingly higher than was expected due to the novelty of the product and the popularity.

Next, examining the relationship between our variables age of initiation and frequency of use on strength of nicotine dependence received from the HONC. A significant correlation between frequency of use in the last 30 days and our dependency summed score confirmed one of our hypotheses. As days used in the last 30 days increased our dependency summed score also increased. However, we originally thought that age of initiation would have a significant

correlation with the dependency summed score and we found that to be untrue in our results. The direction of the correlation is what has been shown in prior research (Park et al. 2004), as age decreases (younger) dependency would increase, but was found not significant in the results. The insignificance could be attributed to the small sample size and similar demographical age of the population heavily coming from the sophomore and junior classes.

Additional tests compared the age of initiation for conventional cigarettes and vaping and found there to be a lower age of smoking initiation compared to vaping. This is not what would be expected as the researchers have seen the vaping rates for high school reach 28% and middle school to 11% both surpassing the conventional cigarette rates among these groups (CDC, 2019). The reason for this could be attributed to sampling of only college students and them being older and the relatively new introduction of vaping. Including middle school and high school students into the population might drive down the average age of initiation of vaping, while conventional cigarettes would stay very similar to the rates we saw in our results.

Limitations

Limitations of this study include the use of convenience sampling of college students in KIN 210 at Missouri State University and the demographics of this population, which effects the ability to generalize to other populations. Self-report of the responses, which can be susceptible to social desirability bias and performance expectations due to nature of the questionnaire on substance use. The students must also recall on past events and rely on their memory for the accuracy of their information. The study does not indicate risk among certain levels of nicotine dependence based on the responses. The modified Hooked-on Nicotine Checklist was used inside a larger parent survey that could affect the responses. The results of the study are also

limited by the reliability of the m-HONC scale responses. The study, being cross-sectional, will not be able to look at longitudinal data. Additionally, sample size and data collection were limited due to our sampling procedure using only the KIN 210 classes. Due to the sampling procedure the study received a small sample size and readers should take that into consideration when viewing the results from the study. When beginning this research in 2018 public knowledge of vaping was low, but due to the number of illnesses and deaths linked to vaping usage in 2019, specifically THC infused, caused an uproar and led to many public health initiatives to increase knowledge and awareness (CDC, 2019) (Layden et al., 2019).

Recommendations for Future Research

While there are several limitations in the study it still highlights the knowledge gap on vaping products in 2019. The m-HONC scale, with better sample size, could be a useful tool in assessing strength of nicotine dependence among EVP users, given the simplicity of the questions, emphasis on vaping, and the use of the scale for this population. Additional research focusing on intervention strategies for adolescent EVP users would be beneficial as there is an epidemic of nicotine addiction in 2019. Further examination of the age of initiation factor should be explored to examine the impact on future addiction, specific to vaping. Using the m-HONC to sample middle school and high school students to check the reliability and validity across a different age population. Future research should also include dual use analyses as there is a large amount of dual use between EVP and cigarettes.

REFERENCES

- ACHA Reference Group Data Report Spring 2019. Retrieved November 1, 2019, from https://www.acha.org/NCHA/ACHA-NCHA_Data/Publications_and_Reports/NCHA/Data/Reports_ACHA-NCHAIic.aspx
- AHA. (2018). Chemicals used to flavor tobacco may damage blood vessels. Retrieved November 12, 2019, from <https://www.heart.org/en/news/2018/07/12/chemicals-used-to-flavor-tobacco-may-damage-blood-vessels>
- Arrazola RA, Singh T, Corey CG, Husten CG, Neff Lj, et al. (2015). Youth Tobacco use: Results from the 2014 National Youth Tobacco Survey Title. MMWR. Morbidity and Mortality Weekly Report, 64, 381-85.
- Bach, L (2019). JUUL and Youth: Rising E-Cigarette Popularity. Retrieved November 11, 2019, from Campaign for Tobacco Free Kids website: <https://www.tobaccofreekids.org/assets/factsheets/0394.pdf>
- Benowitz, NL (2010). Nicotine addiction. The New England Journal of Medicine, 362, 2295-303.
- CDC (2017). Youth Risk Behavior Surveillance System. Retrieved April 21, 2019, from <https://www.cdc.gov/healthyyouth/data/yrbs/results.htm>
- CDC (2018). National Youth Tobacco Survey. Retrieved April 21, 2019, from https://www.cdc.gov/tobacco/data_statistics/surveys/nyts/index.htm
- CDC (2019). Quick Facts on the Risks of E-cigarettes for Kids, Teens, and Young Adults. Retrieved October 18, 2019, from https://www.cdc.gov/tobacco/basic_information/e-cigarettes/Quick-Facts-on-the-Risks-of-E-cigarettes-for-Kids-Teens-and-Young-Adults.html
- Chen, X, Stacy, A, Zheng, H, Shan, J, Spruijt-Metz, D, Unger, J, et al. Ph D, A. J. C. (2003). Sensations from initial exposure to nicotine predicting adolescent smoking in China: a potential measure of vulnerability to nicotine. Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco, 5, 455–63.

- Cooper, M, Creamer, MR, Ly, C, Crook, B, Harrell, MB, & Perry, CL (2016). Social Norms, Perceptions and Dual/Poly Tobacco Use among Texas Youth. *American Journal of Health Behavior*, 40(6), 761–770.
- Cullen, KA, Gentzke, AS, Sawdey, MD, Chang, JT, Anic, GM, Wang, TW et al. King, B. A. (2019). e-Cigarette Use Among Youth in the United States, 2019. *JAMA*.
- Davis, M, Kauffman, A, Singer, D, Gebremariam, A, & Clark, S (2013). Adults Worry e-Cigarettes Will Encourage Kids to Start Smoking Tobacco. *Mott Poll Report*, 20(1).
- Dawkins, L, Kimber, C, Doig, M, Feyerabend, C, & Corcoran, O (2016). Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. *Psychopharmacology*, 233, 2933–41.
- Demissie, Z, Everett Jones, S, Clayton, HB, & King, BA (2017). Adolescent Risk Behaviors and Use of Electronic Vapor Products and Cigarettes. *Pediatrics*, 139(2), e20162921.
- Dierker, L, Swendsen, J, Rose, J, He, J, & Merikangas, K (2012). Transitions to Regular Smoking and Nicotine Dependence in the Adolescent National Comorbidity Survey (NCS-A). In *Annals of Behavioral Medicine* (Vol. 43).
- DiFranza, JR, Huang, W, & King, J (2012). Neuroadaptation in nicotine addiction: update on the sensitization-homeostasis model. *Brain Sciences*, 2, 523-52.
- DiFranza, JR, Savageau, JA, Fletcher, K, Ockene, JK, Rigotti, NA, McNeill, AD, Wood, C, et al. (2002). Measuring the Loss of Autonomy Over Nicotine Use in Adolescents: The DANDY (Development and Assessment of Nicotine Dependence in Youths) Study. *JAMA Pediatrics*, 156, 397–403.
- Duke, JC, Lee, YO, Kim, AE, Watson, KA, Arnold, KY, Nonnemaker, JM, & Porter, L (2014). Exposure to Electronic Cigarette Television Advertisements Among Youth and Young Adults. *Pediatrics*, 134, 29-36.

E-cigarette use by teens triples; health officials warn of nicotine's dangers. (2015). The Brown University Child and Adolescent Behavior Letter, 31, 4–5.

Farsalinos, KE, Voudris, V, & Poulas, K (2015). E-cigarettes generate high levels of aldehydes only in “dry puff” conditions. *Addiction*, 110, 1352–56.

FDA (2019). FDA 's Deeming Regulations for E- Cigarettes, Cigars, and All Other Tobacco Products. Retrieved November 2, 2019, from <https://www.fda.gov/tobaccoproducts/labeling/rulesregulationsguidance/ucm394909.htm>

Goniewicz, ML, Knysak, J, Gawron, M, Kosmider, L, Sobczak, A, Kurek, J, Benowitz, N, et al. (2014). Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tobacco Control*, 23, 133–39.

Hu, M, Griesler, P, Schaffran, C, & Kandel, D (2011). Risk and protective factors for nicotine dependence in adolescence. *Journal of Child Psychology & Psychiatry*, 52, 1063–72.

Hubbs, AF, Cumpston, AM, Goldsmith, WT, Battelli, LA, Kashon, ML, Jackson, MC, Sriram, K, et al. (2012). Respiratory and olfactory cytotoxicity of inhaled 2,3-pentanedione in Sprague-Dawley rats. *The American Journal of Pathology*, 181, 829–44.

Hyman, WV, & Brown, SL (2012). E-cigarettes and Vaping: Risk Reduction and Risk Prevention. 69, 13–19.

Jacobsen, LK, Krystal, JH, Mencl, WE, Westerveld, M, Frost, SJ, & Pugh, KR (2005). Effects of smoking and smoking abstinence on cognition in adolescent tobacco smokers. *Biological Psychiatry*, 57, 56–66.

Johnston, LD, Miech, RA, O'Malley, PM, Bachman, JG, Schulenberg, JE, & Patrick, ME (2019). Monitoring the Future: National survey results on drug use 1975-2018. 2018 Overview: Key findings on adolescent drug use. The National Institute on Drug Abuse at The National Institutes of Health, 1–104.

JUUL (n.d.). Retrieved July 14, 2019, from <https://www.juul.com/>

Kota, D, Martin, BR, & Damaj, MI (2008). Age-dependent differences in nicotine reward and withdrawal in female mice. *Psychopharmacology*, 198, 201-10.

LaVito, A (2018). Popular e-cigarette Juul's sales have surged almost 800 percent over the past year. Retrieved December 8, 2018, from <https://www.cnbc.com/2018/07/02/juul-e-cigarette-sales-have-surged-over-the-past-year.html>.

Layden, JE, Ghinai, I, Pray, I, Kimball, A, Layer, M, Tenforde, M, Meiman, J, et al. (2019). Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Preliminary Report. *New England Journal of Medicine*.

Lynch, B, & Bonnie, R (1994). *The Nature of Nicotine Addiction. Growing up Tobacco Free: Preventing Nicotine Addiction in Children and Youths.*

lyney, TR, Hopke, PK, Zhao, J, & Babaian, S (2012). Comparison of the effects of e-cigarette vapor and cigarette smoke on indoor air quality. *Inhalation Toxicology*, 24, 850–57.

McKelvey, K, Baiocchi, M, & Halpern-Felsher, B (2018). Adolescents' and Young Adults' Use and Perceptions of Pod-Based Electronic Cigarettes. *JAMA Network Open*, 1, e183535.

McKelvey, K, Popova, L, Pepper, JK, Brewer, NT, & Halpern-Felsher, B (2018). Adolescents have unfavorable opinions of adolescents who use e-cigarettes. *PLoS ONE*, 13, 1–10.

Measham, F, O'Brien, K, & Turnbull, G (2016). "Skittles & Red Bull is my favourite flavour": E-cigarettes, smoking, vaping and the changing landscape of nicotine consumption amongst British teenagers – implications for the normalisation debate. *Drugs: Education, Prevention and Policy*, 23, 224–37.

- Miech, RA, O'Malley, PM, Johnston, LD, & Patrick, ME (2016). E-Cigarettes and the Drug Use Patterns of Adolescents. *Nicotine & Tobacco Research: Official Journal of the Society for Research on Nicotine and Tobacco*, 18, 654–59.
- Miech, R, Patrick, ME, O'Malley, PM, & Johnston, LD (2017). What are kids vaping? Results from a national survey of US adolescents. *Tobacco Control*, 26, 386–91.
- Morean, ME, Kong, G, Camenga, DR, Cavallo, DA, & Krishnan-Sarin, S (2015). High School Students' Use of Electronic Cigarettes to Vaporize Cannabis. *Pediatrics*, 136, 611–6.
- Padon, AA, Maloney, EK, & Cappella, JN (2017). Youth-Targeted E-cigarette Marketing in the US Youth-Targeted E-cigarette Marketing in the US. *Tobacco Regulatory Science*, 3, 95–101.
- Park, SM, Son, KY, Lee, YJ, Lee, H.-CS, Kang, JH, Lee, YJ, Yun, YH, et al. (2004). A preliminary investigation of early smoking initiation and nicotine dependence in Korean adults. *Drug & Alcohol Dependence*, 74, 197.
- Rose, JS, Dierker, LC, & Donny, E (2010). Nicotine dependence symptoms among recent onset adolescent smokers. *Drug & Alcohol Dependence*, 106, 126-32.
- Treur, JL, Willemsen, G, Bartels, M, Geels, LM, van Beek, JHDA, Huppertz, C, Vink, JM, et al. (2015). Smoking During Adolescence as a Risk Factor for Attention Problems. *Biological Psychiatry*, 78, 656–63.
- TruthInitiative (2019). How Much Nicotine is in JUUL? Retrieved July 19, 2019, from <https://truthinitiative.org/research-resources/emerging-tobacco-products/how-much-nicotine-juul>
- Tsai, J, Walton, K, Coleman, BN, Sharapova, SR, Johnson, SE, Kennedy, SM, & Caraballo, RS (2018). Reasons for Electronic Cigarette Use Among Middle and High School Students - National Youth Tobacco Survey, United States, 2016. *MMWR. Morbidity and Mortality Weekly Report*, 67, 196–200.

- U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014. Printed with corrections, January 2014.
- U.S. Department of Health and Human Services. E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.
- Van Gucht, D, & Baeyens, F (2016). Health professionals in Flanders perceive the potential health risks of vaping as lower than those of smoking but do not recommend using e-cigarettes to their smoking patients. *Harm Reduction Journal*, 13, 1–8.
- Wellman, RJ, DiFranza, JR, Savageau, JA, Godiwala, S, Friedman, K, & Hazelton, J (2005). Measuring adults' loss of autonomy over nicotine use: The Hooked on Nicotine Checklist. *Nicotine & Tobacco Research*, 7, 157–161.
- Wellman, R, Savageau, J, Godiwala, S, Savageau, N, Friedman, K, Hazelton, J, & DiFranza, JR (2005). A comparison of the Hooked on Nicotine Checklist and the Fagerstrom Test for Nicotine Dependence in adult smokers. 575–80.
- Willett, JG, Bennett, M, Hair, EC, Xiao, H, Greenberg, MS, Harvey, E, Vallone, D, et al. (2019). Recognition, use and perceptions of JUUL among youth and young adults. *Tobacco Control*, 28, 115–6.
- Williams, RS (2015). VapeCons: E-cigarette user conventions. *Journal of Public Health Policy*, 36, 440–51.
- Yuan, M, Loughlin, S, & Leslie, F (2015). Nicotine and the Adolescent Brain. *Journal of Physiology*, 593(16), 3397–3412.
- Zhu, SH, Sun, JY, Bonnevie, E, Cummins, SE, Gamst, A, Yin, L, & Lee, M (2014). Four hundred and sixty brands of e-cigarettes and counting: implications for product regulation. *Tobacco Control*, 23, iii3–iii9.

APPENDICES

Appendix A: IRB Approval Certificate

Date: 4-5-2020

IRB #: IRB-FY2019-345

Title: Adolescents' and Parents' Perceptions and Behaviors Related to Electronic Vapor Products

Creation Date: 11-19-2018

End Date: 2-23-2021

Status: **Approved**

Principal Investigator: Stacy Goddard

Review Board: MSU

Sponsor:

Study History

Submission Type	Initial	Review Type	Expedited	Decision	Approved
Submission Type	Modification	Review Type	Expedited	Decision	Approved
Submission Type	Modification	Review Type	Expedited	Decision	Approved
Submission Type	Modification	Review Type	Expedited	Decision	Approved
Submission Type	Renewal	Review Type	Expedited	Decision	Approved

Key Study Contacts

Member	Stacy Goddard	Role	Principal Investigator	Contact	sgoddard@missouristate.edu
Member	Melinda Novik	Role	Investigator	Contact	melindanovik@missouristate.edu

Member	Stacy Goddard	Role	Primary Contact	Contact sgoddard@missouristate.edu
Member	Joshua Devine	Role	Investigator	Contact devine23@live.missouristate.edu
Member	Riley Galloway	Role	Investigator	Contact rileygalloway@missouristate.edu
Member	Meg Sheppard	Role	Investigator	Contact sheppardm15@ecu.edu
Member	Michelle Morris	Role	Investigator	Contact michelle.morris@polcountyhealth.org

Initial Submission

Investigative Team

Who is the Principal Investigator?

- 1 *This individual will be required to certify the protocol for submission and will be responsible for the overall project and **MUST be a faculty or staff member.***

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Who is the Primary Study Contact?

- 2 *This person, in addition to the Principal Investigator, will be included on all correspondence related to this project. This person may be the Principal Investigator or someone else (**faculty, staff, or student**).*

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Will there be any Co-Principal Investigators participating in this study?

3. *Co-Principal Investigators will also be required to certify the protocol for submission and share overall responsibility with the Principal Investigator for the study. Co-Principal Investigators **MUST be faculty or staff members.***

Yes

✓ No

Will there be any other individuals participating with the investigation?

4

These individuals will be participating as part of the research team, but will not need to certify the protocol submissions, or be included in any correspondence regarding the study. Typically these individuals will be students or individuals from other institutions. Investigators may be faculty, staff, students, or unaffiliated individuals.

✓ Yes

Select the Investigator(s)

No

What is the full title of the research protocol?

1

Adolescents' and Parents' Perceptions and Behaviors Related to Electronic Vapor Products

Abstract/Summary

Please provide a brief description of the project.

2

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). Adolescents have begun using electronic vapor products at an alarming rate while the research related to the health effects of the products is lagging behind. The current data related to youth and adolescents using electronic vapor products has primarily been collected through national surveys that mainly focus on large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

Are you requesting Single IRB Review

3

Single IRB Review is applicable to a study that is being reviewed by another Institution's IRB, in which you wish to rely on the external IRB for review, approval, and oversight.

Yes

✓ No

Does the study require review and oversight of the IRB?

4

Regardless of how these questions are answered, the determination of IRB review and oversight is made by the IRB and this study will still need to be submitted for preliminary review.

Is this study a systematic investigation, following a predetermined plan, for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that includes any of the following:

- 4A
- Collection or analysis of quantitative or qualitative data
 - Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
 - Collection of data using experimental designs such as clinical trials
 - Observation of individual or group behavior
-

☒ Yes
☐ No

Will this study contribute to generalizable knowledge, in that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied? This may include one or more of the following:

- 4B
- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
 - The knowledge contributes to an already established body of knowledge Other investigators, scholars, and practitioners may benefit from this knowledge
 - Publications including journals, papers, dissertations, and theses
-

☒ Yes
☐ No

4C Will this study require obtaining information or biospecimens, through intervention or interaction with an individual that will be used, studied, or analyzed by the investigative team?

☒ Yes
☐ No

Will you be requesting an Exempt Review for this study?

5

In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

☐ Yes
☒ No

6 Is this study receiving internal or external funding?

☐ Yes
☒ No

Does this study contain protected health information (PHI)?

7

PHI is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, such as a diagnosis or treatment.

Yes

✓ No

8 Has all IRB Human Research training been taken through CITI under Missouri State University?

✓ Yes

No

Describe the proposed project in a manner that allows the IRB to gain a sense of the project including:

- The research questions and objectives,
- Key background literature (supportive and contradictory) with references, and The manner in which the proposed project will improve the understanding of the chosen topic.

Research Questions

1. What are the factors that predict the use of electronic vapor products?
2. What is the relationship between frequency of use of electronic vapor products and strength of nicotine dependence.
3. What is the relationship between perceptions of health risk and parental discussion of electronic vapor products?

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). This report was in response to the dramatic increase in use of electronic vapor products in the last several years. For example, use of electronic cigarettes increased among middle school students from 0.6% in 2011 to 4.9% in 2018 and among high school students, the prevalence increased from 1.5% in 2011 to 20.8% in 2018 (Kann et al., 2018). The increase in electronic vapor product use among teens came at the same time as a decrease in traditional tobacco use. From 2011 to 2017, 2.1% of middle school students reported smoking traditional cigarettes, which was a decrease from 4.3% in 2011 (Kann et al., 2018). Likewise, in 2017, 7.6% of high school students reported smoking cigarettes in the past 30 days, which was also a decrease from 15.8% in 2011 (Kann et al., 2018). The decrease in traditional cigarette use among adolescents is a statement to the public health efforts on the national, state, and local levels through prevention, education, and policy developments.

After the success of cigarette use decreasing among adolescents and young adults, it is disturbing that the rates of alternative methods of tobacco delivery systems have emerged and increased dramatically, taking over as the most commonly used tobacco product (National Institute on Drug Abuse, 2018). The health effects of traditional tobacco products have been widely known for decades, however, the immediate and long-term health effects of electronic vapor products are still being researched. Regardless of the method of nicotine delivery, it is well documented that nicotine is one of the most addictive substances and is harmful to brain development in adolescents (CDC, 2018). Many chemicals are also known to be in electronic vapor products, including diacetyl, 2,3 prentanedione, and acetoin, which have been linked to bronchiolitis obliterans (popcorn lung) and other lung diseases (Printz, 2018). However, electronic vapor products, such as e-cigarettes, JUULs, vape pens, e-hookahs, and many others have been marketed as a safer alternative to traditional or

1

combustible tobacco products. With flavor categories such as candy or desserts, coffee, fruit, spice, or alcohol, it is not surprising that adolescents are drawn to the products. The high-tech features of some of the devices are also a draw for teens. Devices that resemble a USB drive or a pen can easily be concealed from parents or teachers and used when and wherever desired, which becomes a real problem for parents and schools in preventing the use of the products.

In May 2016, the Food and Drug Administration (FDA) issued a final rule that allows the agency the authority to have oversight over all tobacco products including electronic vapor products (American Lung Association [ALA], 2018). The FDA implemented policies to restrict the products to youth, prohibit certain flavors, and require warnings on packaging. However, youth-oriented flavors are still being sold from online stores, marketing of vapor products have just recently been removed on some social media outlets, but not all, and vape conventions are still occurring. It is clear that an ecological approach to decreasing the use of electronic vapor products among youth and adolescents is needed to curtail this epidemic. Parents need to be aware of the health effects from electronic vapor products, what they look like, and how exposed to the devices their children are so they can take steps to prevent their child from using electronic vapor products. Partnerships within communities need to be developed to implement policies prohibiting youth from purchasing the devices and pods, schools need to understand the best approach to preventing the use of the devices at school, and adolescents need to be educated on the dangers of using electronic vapor products. Through the ecological approach, eventually a denormalization process will happen and the rates of youth and adolescents using vapor products will decrease, just as it has with tradition smoking.

The current data related to youth and adolescents using electronic vapor products was primarily collected through the Youth Behavioral Risk Surveillance Survey (YBRSS), which is distributed in odd-numbered years by the CDC. Therefore, the data are from a national level and often collected from large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

2 Check all research activities that apply:

Audio, video, digital, or image recordings

Biohazards (e.g., rDNA, infectious agents, select agents, toxins)

- Biological sampling (other than blood)
- Blood drawing
- Class Protocol (or Program or Umbrella Protocol)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics
- Focus groups
- Internet or email data collection
- Materials that may be considered sensitive, offensive, threatening, or degrading
- Non-invasive medical procedures
- Observation of participants
- Oral history
- Placebo
- Record review
- Specimen research
- Surgical procedures
- Surveys, questionnaires, or interviews (one-on-one)
- ✓ Surveys, questionnaires, or interviews(group)
- Other

Describe the procedures and methods planned for carrying out the study. Make sure to include the following:

- Site selection,
- The procedures used to gain permission to carry out research at the selected sites(s),
- Data collection procedures, and
- An overview of the manner in which data will be analyzed.

Provide all information necessary for the IRB to be clear about all of the contact human participants will have with the project.

Design and setting:

The study will be a cross-sectional survey of 6th through 12th grade students and their parents at five rural school districts in Southwest Missouri. The survey will have an informed consent signed by the parents for the child. The child must bring the signed informed consent back to the school for the child to participate in the study. The students will also sign an assent to participate in the survey. Parents of the students will also be asked to participate in the survey and will have the option of either an electronic survey or a hard copy. Each school will determine how they want to distribute the survey to the parents and the students.

Sample:

- 3 The population for this study will be all 6th through 12th grade students whose parents returned the signed informed consent to the school and those students who also signed the assent form. Approximately 1433 students will have the opportunity of participating in the study. Parents or legal guardians of the students will also be surveyed related to their attitudes and knowledge regarding electronic vapor products. Approximately 1433 parents or legal guardians will have the opportunity to participate in the study.

Data Collection: The primary investigator will provide hard copy surveys to the five school districts in spring 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in March, after the spring break holiday. The primary investigator will also provide hard copy surveys for the parents to complete during parent/teacher conferences held at the schools, also in March. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

Confidentiality and security: Participants will not be identified by name with hard copy surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored in a password protected computer also in the primary investigator's locked office. The researchers are the only

persons who will have access to the data.

Attach tests, surveys, questionnaires, and other social-behavioral measurement tools, if applicable.

4

[Teen vaping survey.docx](#)

[Parent Vaping Survey.docx](#)

Attach documentation of site permission, if applicable.

5

[Email from Michelle Morris.docx](#)

Specify the participant population(s).

1

Check all that apply.

✓ Adults

✓ Children (<18 years of age) Adults

with decisional impairment Non-

English speaking

Student research pools (e.g. psychology)

Pregnant women or fetuses

Prisoners

Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program/class/umbrella protocols)

Specify the age(s) of the individuals who may participate in the research.

2

6th grade (11 years) to 12th grade (18 years) and parents or legal guardians

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

3

The participants are 6th through 12th grade students in five public middle schools and four public high schools in Polk County, MO as well as the parents or legal guardians of the students. They are included in the research to help determine the perceptions, and use of vaping among a local teen population. This information will allow health education program planners to better create interventions to prevent local students from initiating use of electronic vapor products. Parents of these students are included in the research to gain an understanding of the current level of knowledge among parents as well as what their perceptions are of teens using electronic vapor

products. This information will also help health education program planners develop relevant programs to educate parents related to electronic vapor products.

- 4 Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval.
-

Approximately 1500 students and 1500 parents

- 5 Describe what time commitment will be required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.
-

The only interaction will be the completion of the survey which will take approximately 15-20 minutes.

- 6 Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.
-

The primary investigator is partnering with the administrator of the Polk County Health Department on this research. The administrator has contacted the schools in Polk County and asked if the school would participate in the survey. Five middle schools in the county and four high schools in the county have confirmed that they would like to participate in the research. See attached email from Michelle Morris.

- Describe the recruitment process; including the setting in which recruitment will take place.
-

The primary investigator will provide hard copy surveys to the five school districts in spring 2019 to be distributed at their convenience to the students. The schools will also have the ability to have

- 7 students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in April. The primary investigator will also provide hard copy surveys for the parents to complete. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

Attach recruitment materials (ads, flyers, website postings, recruitment letters, and oral/written scripts), if applicable .

- 8 Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement, etc.) to participate in the research study?
-

Yes

✓ No

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence.

1

Consider the range of risks - physical, psychological, social, legal, and economic.

There are not risks to the students or parents beyond what is normally encountered in a regular day.

Discuss the steps that will be taken to minimize risks and the likelihood of harm.

Although there are no inherent risks in completing the survey, the following paragraph will be read to students before they take the survey.

Thank you for choosing to participate in this study. You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as

2

well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large “tank” devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and not looking at other students’ papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Describe the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.

3

There are no direct benefits to the students or parents in the study.

Discuss any potential indirect benefits to future subjects, science, and society.

4

The younger students and the parents may benefit later from the educational interventions developed from the information from the study. Other indirect benefits will be reducing the number of teens who start using electronic vapor products in Polk County through prevention programs created from results gained from this study. Other indirect benefits may be the development of cessation programs for teens and/or parents who use electronic vapor products. Through education and program development a shift in the social norm of using an electronic vapor product may change over time so fewer teens choose to start using the products as we've seen with traditional tobacco products.

Describe how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

5

The risks to the students and parents is minimal due to the questions being asked. The knowledge gained from the study is important to local program planners to understand the type of interventions that need to take place in their county. Currently, only national data has been collected related to teens and their perceptions, use, and addiction to electronic vapor products and that information has come from large urban school districts. Understanding what is happening at the local level allows for more direct and targeted interventions to take place. There also have not been any studies conducted to determine the current level of knowledge, perception, and use of electronic vapor products from parents as it relates to their child. This information will have a direct affect on the development of interventions that use an ecological approach, which is much more effective than just intervening only at the intrapersonal level.

From the list below, indicate how consent will be obtained for this study.

1

Check all that apply.

- ✓ Written/signed consent by the subject
- ✓ Written/signed consent (permission) for a minor by a Parent or Legal Guardian
- Written/signed consent by a Legally Authorized Representative (for adults incapable of consenting)
- Request for waiver of documentation of consent (verbal consent, anonymous surveys, etc.)
- Waiver of parental permission
- Waiver of consent (consent will not be obtained from subjects)

Describe the consent process including where and by whom the subjects will be approached, the plans to ensure the privacy of the subjects and the measures to ensure that subjects understand the nature of the study, its procedures, risks and benefits and that they freely grant their consent.

The schools will distribute an informed consent to the parents of 6th through 12th grade students explaining the study and asking them to return the signed informed consent for their child to participate in the survey. Only students who have a signed informed consent will be allowed to participate in the survey. The students who are allowed by their parents to participate will also sign an assent form before they participate in the survey.

2

Before each class participates in the survey, the students will be read information related to taking the survey, asking them to keep their information private and not to look at other student's papers or computers. The information will be as follows:

You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large "tank" devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and

not looking at other students' papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Attach all consent and assent documents here:

[ASSENT_Children_Under_18.doc](#)

[Parent Consent Form.docx](#)

[EVPOptIN.docx](#)

Missouri State University is committed to keeping data and information secure. Please review the Missouri Ste University [Information Security Policies](#). Discuss you project with the MSU Information Security Office or your College's IT support staff if you have questions about how to handle your data appropriately.

Statement of Principal Investigator Responsibility for Data

- 1 The principal investigator of this study is responsible for the storage, oversight, and disposal of all data associated with this study. Data will not be disseminated without the explicit approval of the principal investigator, and identifying information associated with the data will not be shared.
-

✓ By checking this box, all personnel associated with this study understand and agree to the Statement of Principal Investigator Responsibility for Data.

How will the data for this study be collected/stored?

2

Check all that apply.

✓ Electronic storage format
On paper

Describe where the data will be stored (e.g., paper forms, flash drives or removable media, desktop or laptop computer, server, research storage area network, external

source) and describe the plan to ensure the security and confidentiality of the records (e.g., locked office, locked file cabinet, password-protected computer or files, encrypted data files, database limited to coded data, master list stored in separate location).

At minimum, physical data should always be secured by lock and key when stored. Electronic data should be stored on University secure servers whenever possible (Office

- 3 *365 or other secure campus server). If data has to be stored off campus, the files should be encrypted and the device password protected. Additionally, any data to be shared outside the University network will require a SUDERS request be filed and approved. See <https://mis.missouristate.edu/Central/suders/create>*

Both electronic and paper forms will be used in the research.

Participants will not be identified by name with hard copy or online surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored on the primary investigator's campus computer in a secure campus server. The primary investigator's campus computer is also password protected in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Describe how data will be disposed of and when disposal will occur.

At minimum, Federal regulations require research records to be retained for at least 3

- 4 *years after the completion of the research (45 CFR 46). Research that involves identifiable health information is subject to HIPAA regulations, which require records to be retained for at least 6 years after a participant has signed an authorization. Finally, funded research projects may require longer retention periods, you may need to follow the sponsoring agency guidelines.*

All research records will be shredded and disposed of 3 years after the research study has concluded,

1 Please include any additional information about the study below.

Please include any additional documents that aren't covered within the application.

2

Modification Submission

Modification Summary

Please make changes to the original protocol sections below. In addition, provide a summary of the changes by completing the questions on this page.

To which of the following aspects of research does this modification request apply?

A.

Check all that apply.

Change in personnel

Research design

Risks to participants or others in relation to anticipated benefits

✓ Participant selection or recruitment process

Consent process and/or compensation Methods
for documenting consent

Change in supporting documentation or attachments

Potential willingness of research participants to continue to take part in this study

Monitoring of the data being collected

Privacy of the research participants and/or confidentiality of research participants' data

Other

Please provide a brief rationale for each of the changes being requested.

- B. The participants will be recruited from El Dorado Springs, Strafford, and Niangua school districts during summer school of 2019. The original Polk County schools will have participants recruited in the fall of 2019. The change is due to not being able to collect data in Spring 2019 because it was too close to the end of the school year when the original IRB was approved. The new schools will allow a pilot test of the survey without having the potential of participants taking the survey twice (once this summer and once in the fall). All protocol will remain the same with allowing the schools to determine if they want to use an electronic or paper survey. There is a potential of 500 students and their parents who will complete the survey in the summer of 2019.

Who is the Principal Investigator?

- 1 *This individual will be required to certify the protocol for submission and will be responsible for the overall project and **MUST be a faculty or staff member.***

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Who is the Primary Study Contact?

- 2 *This person, in addition to the Principal Investigator, will be included on all correspondence related to this project. This person may be the Principal Investigator or someone else (**faculty, staff, or student**).*

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Will there be any Co-Principal Investigators participating in this study?

3. *Co-Principal Investigators will also be required to certify the protocol for submission and share overall responsibility with the Principal Investigator for the study. Co-Principal Investigators **MUST be faculty or staff members.***

Yes

✓ No

Will there be any other individuals participating with the investigation?

4

These individuals will be participating as part of the research team, but will not need to certify the protocol submissions, or be included in any correspondence regarding the study. Typically these individuals will be students or individuals from other institutions. Investigators may be faculty, staff, students, or unaffiliated individuals.

✓ Yes

Select the Investigator(s)

No

What is the full title of the research protocol?

1

Adolescents' and Parents' Perceptions and Behaviors Related to Electronic Vapor Products

Abstract/Summary

Please provide a brief description of the project.

2

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). Adolescents have begun using electronic vapor products at an alarming rate while the research related to the health effects of the products is lagging behind. The current data related to youth and adolescents using electronic vapor products has primarily been collected through national surveys that mainly focus on large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

Are you requesting Single IRB Review

3

Single IRB Review is applicable to a study that is being reviewed by another Institution's IRB, in which you wish to rely on the external IRB for review, approval, and oversight.

Yes

✓ No

Does the study require review and oversight of the IRB?

4

Regardless of how these questions are answered, the determination of IRB review and oversight is made by the IRB and this study will still need to be submitted for preliminary review.

Is this study a systematic investigation, following a predetermined plan, for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that includes any of the following:

- 4A
- Collection or analysis of quantitative or qualitative data
 - Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
 - Collection of data using experimental designs such as clinical trials
 - Observation of individual or group behavior
-

☒ Yes
☐ No

Will this study contribute to generalizable knowledge, in that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied? This may include one or more of the following:

- 4B
- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
 - The knowledge contributes to an already established body of knowledge Other investigators, scholars, and practitioners may benefit from this knowledge
 - Publications including journals, papers, dissertations, and theses
-

☒ Yes
☐ No

4C Will this study require obtaining information or biospecimens, through intervention or interaction with an individual that will be used, studied, or analyzed by the investigative team?

☒ Yes
☐ No

Will you be requesting an Exempt Review for this study?

5

In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

☐ Yes
☒ No

6 Is this study receiving internal or external funding?

☐ Yes
☒ No

Does this study contain protected health information (PHI)?

7

PHI is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, such as a diagnosis or treatment.

Yes

✓ No

8 Has all IRB Human Research training been taken through CITI under Missouri State University?

✓ Yes

No

Describe the proposed project in a manner that allows the IRB to gain a sense of the project including:

- The research questions and objectives,
- Key background literature (supportive and contradictory) with references, and The manner in which the proposed project will improve the understanding of the chosen topic.

Research Questions

1. What are the factors that predict the use of electronic vapor products?
2. What is the relationship between frequency of use of electronic vapor products and strength of nicotine dependence.
3. What is the relationship between perceptions of health risk and parental discussion of electronic vapor products?

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). This report was in response to the dramatic increase in use of electronic vapor products in the last several years. For example, use of electronic cigarettes increased among middle school students from 0.6% in 2011 to 4.9% in 2018 and among high school students, the prevalence increased from 1.5% in 2011 to 20.8% in 2018 (Kann et al., 2018). The increase in electronic vapor product use among teens came at the same time as a decrease in traditional tobacco use. From 2011 to 2017, 2.1% of middle school students reported smoking traditional cigarettes, which was a decrease from 4.3% in 2011 (Kann et al., 2018). Likewise, in 2017, 7.6% of high school students reported smoking cigarettes in the past 30 days, which was also a decrease from 15.8% in 2011 (Kann et al., 2018). The decrease in traditional cigarette use among adolescents is a statement to the public health efforts on the national, state, and local levels through prevention, education, and policy developments.

After the success of cigarette use decreasing among adolescents and young adults, it is disturbing that the rates of alternative methods of tobacco delivery systems have emerged and increased dramatically, taking over as the most commonly used tobacco product (National Institute on Drug Abuse, 2018). The health effects of traditional tobacco products have been widely known for decades, however, the immediate and long-term health effects of electronic vapor products are still being researched. Regardless of the method of nicotine delivery, it is well documented that nicotine is one of the most addictive substances and is harmful to brain development in adolescents (CDC, 2018). Many chemicals are also known to be in electronic vapor products, including diacetyl, 2,3 prentanedione, and acetoin, which have been linked to bronchiolitis obliterans (popcorn lung) and other lung diseases (Printz, 2018). However, electronic vapor products, such as e-cigarettes, JUULs, vape pens, e-hookahs, and many others have been marketed as a safer alternative to traditional or

1

combustible tobacco products. With flavor categories such as candy or desserts, coffee, fruit, spice, or alcohol, it is not surprising that adolescents are drawn to the products. The high-tech features of some of the devices are also a draw for teens. Devices that resemble a USB drive or a pen can easily be concealed from parents or teachers and used when and wherever desired, which becomes a real problem for parents and schools in preventing the use of the products.

In May 2016, the Food and Drug Administration (FDA) issued a final rule that allows the agency the authority to have oversight over all tobacco products including electronic vapor products (American Lung Association [ALA], 2018). The FDA implemented policies to restrict the products to youth, prohibit certain flavors, and require warnings on packaging. However, youth-oriented flavors are still being sold from online stores, marketing of vapor products have just recently been removed on some social media outlets, but not all, and vape conventions are still occurring. It is clear that an ecological approach to decreasing the use of electronic vapor products among youth and adolescents is needed to curtail this epidemic. Parents need to be aware of the health effects from electronic vapor products, what they look like, and how exposed to the devices their children are so they can take steps to prevent their child from using electronic vapor products. Partnerships within communities need to be developed to implement policies prohibiting youth from purchasing the devices and pods, schools need to understand the best approach to preventing the use of the devices at school, and adolescents need to be educated on the dangers of using electronic vapor products. Through the ecological approach, eventually a denormalization process will happen and the rates of youth and adolescents using vapor products will decrease, just as it has with tradition smoking.

The current data related to youth and adolescents using electronic vapor products was primarily collected through the Youth Behavioral Risk Surveillance Survey (YBRSS), which is distributed in odd-numbered years by the CDC. Therefore, the data are from a national level and often collected from large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

2 Check all research activities that apply:

Audio, video, digital, or image recordings

Biohazards (e.g., rDNA, infectious agents, select agents, toxins)

- Biological sampling (other than blood)
- Blood drawing
- Class Protocol (or Program or Umbrella Protocol)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics
- Focus groups
- Internet or email data collection
- Materials that may be considered sensitive, offensive, threatening, or degrading
- Non-invasive medical procedures
- Observation of participants
- Oral history
- Placebo
- Record review
- Specimen research
- Surgical procedures
- Surveys, questionnaires, or interviews (one-on-one)
- ✓ Surveys, questionnaires, or interviews(group)
- Other

Describe the procedures and methods planned for carrying out the study. Make sure to include the following:

- Site selection,
- The procedures used to gain permission to carry out research at the selected sites(s),
- Data collection procedures, and
- An overview of the manner in which data will be analyzed.

Provide all information necessary for the IRB to be clear about all of the contact human participants will have with the project.

Design and setting:

The study will be a cross-sectional survey of 6th through 12th grade students and their parents at five rural school districts in Southwest Missouri. The survey will have an informed consent signed by the parents for the child. The child must bring the signed informed consent back to the school for the child to participate in the study. The students will also sign an assent to participate in the survey. Parents of the students will also be asked to participate in the survey and will have the option of either an electronic survey or a hard copy. Each school will determine how they want to distribute the survey to the parents and the students.

Sample:

- 3 The population for this study will be all 6th through 12th grade students whose parents returned the signed informed consent to the school and those students who also signed the assent form. Approximately 1433 students will have the opportunity of participating in the study. Parents or legal guardians of the students will also be surveyed related to their attitudes and knowledge regarding electronic vapor products. Approximately 1433 parents or legal guardians will have the opportunity to participate in the study.

Data Collection: The primary investigator will provide hard copy surveys to the five school districts in spring 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in March, after the spring break holiday. The primary investigator will also provide hard copy surveys for the parents to complete during parent/teacher conferences held at the schools, also in March. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

Confidentiality and security: Participants will not be identified by name with hard copy surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored in a password protected computer also in the primary investigator's locked office. The researchers are the only

persons who will have access to the data.

Attach tests, surveys, questionnaires, and other social-behavioral measurement tools, if applicable.

4

[Teen vaping survey.docx](#)

[Parent Vaping Survey.docx](#)

Attach documentation of site permission, if applicable.

5

[Email from Michelle Morris.docx](#)

Specify the participant population(s).

1

Check all that apply.

- ✓ Adults
- ✓ Children (<18 years of age) Adults
with decisional impairment Non-
English speaking
Student research pools (e.g. psychology)
Pregnant women or fetuses
Prisoners
Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program/class/umbrella protocols)

Specify the age(s) of the individuals who may participate in the research.

2

6th grade (11 years) to 12th grade (18 years) and parents or legal guardians

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

3

The participants are 6th through 12th grade students in five public middle schools and four public high schools in Polk County, MO as well as the parents or legal guardians of the students. They are included in the research to help determine the perceptions, and use of vaping among a local teen population. This information will allow health education program planners to better create interventions to prevent local students from initiating use of electronic vapor products. Parents of theses students are included in the research to gain an understanding of the current level of knowledge among parents as well as what their perceptions are of teens using electronic vapor

products. This information will also help health education program planners develop relevant programs to educate parents related to electronic vapor products.

The survey will be distributed to El Dorado Springs, Strafford, and Niangua 6th through 12th grade summer school students and their parents in the summer of 2019. These students and parents will be recruited to conduct a pilot test of the survey so the potential of duplicating participants is eliminated.

- 4 Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval.
-

Approximately 1500 students and 1500 parents for Polk county schools, and 500 students and 500 parents for El Dorado Springs, Niangua, and Strafford schools during the summer of 2019

- 5 Describe what time commitment will be required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.
-

The only interaction will be the completion of the survey which will take approximately 15-20 minutes.

Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

- 6 The primary investigator is partnering with the administrator of the Polk County Health Department on this research. The administrator has contacted the schools in Polk County and asked if the school would participate in the survey. Five middle schools in the county and four high schools in the county have confirmed that they would like to participate in the research. See attached email from Michelle Morris.
-

The primary investigator has been in contact with administrators at El Dorado Springs, Strafford, and

Niangua schools. Niangua schools have given definite approval of implementing the survey during the summer of 2019. The primary investigator is waiting on approval from both El Dorado Springs and Strafford schools.

Describe the recruitment process; including the setting in which recruitment will take place.

7

The primary investigator will provide hard copy surveys to the five school districts in spring 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in April. The primary investigator will also provide hard copy surveys for the parents to complete. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

The primary investigator will provide hard copy or electronic surveys to the school districts who chose to participate in the summer of 2019 to be distributed at their convenience to the students after getting informed consents from the students' parents. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in June. The primary investigator will also provide hard copy or electronic surveys for the parents to complete. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

Attach recruitment materials (ads, flyers, website postings, recruitment letters, and oral/written scripts), if applicable .

- 8 Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement, etc.)to participate in the research study?
-

Yes

✓ No

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence.

1

Consider the range of risks - physical, psychological, social, legal, and economic.

There are not risks to the students or parents beyond what is normally encountered in a regular day.

Discuss the steps that will be taken to minimize risks and the likelihood of harm.

Although there are no inherent risks in completing the survey, the following paragraph will be read to students before they take the survey.

Thank you for choosing to participate in this study. You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as

2

well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large “tank” devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and not looking at other students’ papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Describe the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.

3

There are no direct benefits to the students or parents in the study.

Discuss any potential indirect benefits to future subjects, science, and society.

4

The younger students and the parents may benefit later from the educational interventions developed from the information from the study. Other indirect benefits will be reducing the number of teens who start using electronic vapor products in Polk County through prevention programs created from results gained from this study. Other indirect benefits may be the development of cessation programs for teens and/or parents who use electronic vapor products. Through education and program development a shift in the social norm of using an electronic vapor product may change over time so fewer teens choose to start using the products as we've seen with traditional tobacco products.

Describe how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

5

The risks to the students and parents is minimal due to the questions being asked. The knowledge gained from the study is important to local program planners to understand the type of interventions that need to take place in their county. Currently, only national data has been collected related to teens and their perceptions, use, and addiction to electronic vapor products and that information has come from large urban school districts. Understanding what is happening at the local level allows for more direct and targeted interventions to take place. There also have not been any studies conducted to determine the current level of knowledge, perception, and use of electronic vapor products from parents as it relates to their child. This information will have a direct affect on the development of interventions that use an ecological approach, which is much more effective than just intervening only at the intrapersonal level.

From the list below, indicate how consent will be obtained for this study.

1

Check all that apply.

- ✓ Written/signed consent by the subject
- ✓ Written/signed consent (permission) for a minor by a Parent or Legal Guardian
- Written/signed consent by a Legally Authorized Representative (for adults incapable of consenting)
- Request for waiver of documentation of consent (verbal consent, anonymous surveys, etc.)
- Waiver of parental permission
- Waiver of consent (consent will not be obtained from subjects)

Describe the consent process including where and by whom the subjects will be approached, the plans to ensure the privacy of the subjects and the measures to ensure that subjects understand the nature of the study, its procedures, risks and benefits and that they freely grant their consent.

The schools will distribute an informed consent to the parents of 6th through 12th grade students explaining the study and asking them to return the signed informed consent for their child to participate in the survey. Only students who have a signed informed consent will be allowed to participate in the survey. The students who are allowed by their parents to participate will also sign an assent form before they participate in the survey.

2

Before each class participates in the survey, the students will be read information related to taking the survey, asking them to keep their information private and not to look at other student's papers or computers. The information will be as follows:

You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large "tank" devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and

not looking at other students' papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Attach all consent and assent documents here:

[ASSENT_Children_Under_18.doc](#)

[Parent Consent Form.docx](#)

[EVPOptIN.docx](#)

Missouri State University is committed to keeping data and information secure. Please review the Missouri Ste University [Information Security Policies](#). Discuss you project with the MSU Information Security Office or your College's IT support staff if you have questions about how to handle your data appropriately.

Statement of Principal Investigator Responsibility for Data

- 1 The principal investigator of this study is responsible for the storage, oversight, and disposal of all data associated with this study. Data will not be disseminated without the explicit approval of the principal investigator, and identifying information associated with the data will not be shared.
-

✓ By checking this box, all personnel associated with this study understand and agree to the Statement of Principal Investigator Responsibility for Data.

How will the data for this study be collected/stored?

2

Check all that apply.

✓ Electronic storage format
On paper

Describe where the data will be stored (e.g., paper forms, flash drives or removable media, desktop or laptop computer, server, research storage area network, external

source) and describe the plan to ensure the security and confidentiality of the records (e.g., locked office, locked file cabinet, password-protected computer or files, encrypted data files, database limited to coded data, master list stored in separate location).

At minimum, physical data should always be secured by lock and key when stored. Electronic data should be stored on University secure servers whenever possible (Office

- 3 *365 or other secure campus server). If data has to be stored off campus, the file should be encrypted and the device password protected. Additionally, any data to be shared outside the University network will require a SUDERS request be filed and approved. See <https://mis.missouristate.edu/Central/suders/create>*

Both electronic and paper forms will be used in the research.

Participants will not be identified by name with hard copy or online surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored on the primary investigator's campus computer in a secure campus server. The primary investigator's campus computer is also password protected in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Describe how data will be disposed of and when disposal will occur.

At minimum, Federal regulations require research records to be retained for at least 3

- 4 *years after the completion of the research (45 CFR 46). Research that involves identifiable health information is subject to HIPAA regulations, which require records to be retained for at least 6 years after a participant has signed an authorization. Finally, funded research projects may require longer retention periods, you may need to follow the sponsoring agency guidelines.*

All research records will be shredded and disposed of 3 years after the research study has concluded,

1 Please include any additional information about the study below.

Please include any additional documents that aren't covered within the application.

2

Modification Submission

Modification Summary

Please make changes to the original protocol sections below. In addition, provide a summary of the changes by completing the questions on this page.

To which of the following aspects of research does this modification request apply?

A.

Check all that apply.

✓ Change in personnel

Please include the name of the researcher(s) added to section 1 and attach their CITI training certificates in section 9.

Research design

Risks to participants or others in relation to anticipated benefits

Participant selection or recruitment process

Consent process and/or compensation

Methods for documenting consent

Change in supporting documentation or attachments

Potential willingness of research participants to continue to take part in this study

Monitoring of the data being collected

Privacy of the research participants and/or confidentiality of research participants' data

✓ Other

Please describe.

After completing a pilot test of the surveys, I have modified the parent and student surveys for easier analysis and changed some of the questions to get more definitive information. I also updated the methods section as we will collect informed consents for the students from their parents at the parent teacher conferences being held in Oct. rather than sending informed consents home with the students to be returned to the school.

Please provide a brief rationale for each of the changes being requested.

Two people who are going to help with the research need to be added so they can have access to the data.

B.

The surveys needed to be modified for easier analyzing and for more definitive information after completing the pilot test of the survey.

The methods for collecting parent surveys and informed consents for the students has changed to simplify the process and so the primary investigator will have the completed informed consents at all times.

Who is the Principal Investigator?

- 1 *This individual will be required to certify the protocol for submission and will be responsible for the overall project and **MUST be a faculty or staff member.***

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Who is the Primary Study Contact?

- 2 *This person, in addition to the Principal Investigator, will be included on all correspondence related to this project. This person may be the Principal Investigator or someone else (**faculty, staff, or student**).*

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Will there be any Co-Principal Investigators participating in this study?

3. *Co-Principal Investigators will also be required to certify the protocol for submission and share overall responsibility with the Principal Investigator for the study. Co-Principal Investigators **MUST be faculty or staff members.***

Yes

✓ No

Will there be any other individuals participating with the investigation?

4

These individuals will be participating as part of the research team, but will not need to certify the protocol submissions, or be included in any correspondence regarding the study. Typically these individuals will be students or individuals from other institutions. Investigators may be faculty, staff, students, or unaffiliated individuals.

✓ Yes

Select the Investigator(s)

No

What is the full title of the research protocol?

1

Adolescents' and Parents' Perceptions and Behaviors Related to Electronic Vapor Products

Abstract/Summary

Please provide a brief description of the project.

2

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). Adolescents have begun using electronic vapor products at an alarming rate while the research related to the health effects of the products is lagging behind. The current data related to youth and adolescents using electronic vapor products has primarily been collected through national surveys that mainly focus on large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

Are you requesting Single IRB Review

3

Single IRB Review is applicable to a study that is being reviewed by another Institution's IRB, in which you wish to rely on the external IRB for review, approval, and oversight.

Yes

✓ No

Does the study require review and oversight of the IRB?

4

Regardless of how these questions are answered, the determination of IRB review and oversight is made by the IRB and this study will still need to be submitted for preliminary review.

Is this study a systematic investigation, following a predetermined plan, for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that includes any of the following:

- 4A
- Collection or analysis of quantitative or qualitative data
 - Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
 - Collection of data using experimental designs such as clinical trials
 - Observation of individual or group behavior
-

✓ Yes
No

Will this study contribute to generalizable knowledge, in that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied? This may include one or more of the following:

- 4B
- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
 - The knowledge contributes to an already established body of knowledge Other investigators, scholars, and practitioners may benefit from this knowledge
 - Publications including journals, papers, dissertations, and theses
-

✓ Yes
No

4C Will this study require obtaining information or biospecimens, through intervention or interaction with an individual that will be used, studied, or analyzed by the investigative team?

☒ Yes
☐ No

Will you be requesting an Exempt Review for this study?

5

In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

☐ Yes
☒ No

6 Is this study receiving internal or external funding?

☐ Yes
☒ No

Does this study contain protected health information (PHI)?

7

PHI is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, such as a diagnosis or treatment.

Yes

✓ No

8 Has all IRB Human Research training been taken through CITI under Missouri State University?

Yes

✓ No

Training Certificates

8A *Please upload all training certificates taken outside of CITI, or CITI certificates completed through another institution.*

[Sheppard - CITI Program - Feb 2023.pdf](#)

[Michelle CITI training.pdf](#)

Describe the proposed project in a manner that allows the IRB to gain a sense of the project including:

- The research questions and objectives,
- Key background literature (supportive and contradictory) with references, and The manner in which the proposed project will improve the understanding of the chosen topic.

Research Questions

1. What are the factors that predict the use of electronic vapor products?
2. What is the relationship between frequency of use of electronic vapor products and strength of nicotine dependence.
3. What is the relationship between perceptions of health risk and parental discussion of electronic vapor products?

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). This report was in response to the dramatic increase in use of electronic vapor products in the last several years. For example, use of electronic cigarettes increased among middle school students from 0.6% in 2011 to 4.9% in 2018 and among high school students, the prevalence increased from 1.5% in 2011 to 20.8% in 2018 (Kann et al., 2018). The increase in electronic vapor product use among teens came at the same time as a decrease in traditional tobacco use. From 2011 to 2017, 2.1% of middle school students reported smoking traditional cigarettes, which was a decrease from 4.3% in 2011 (Kann et al., 2018). Likewise, in 2017, 7.6% of high school students reported smoking cigarettes in the past 30 days, which was also a decrease from 15.8% in 2011 (Kann et al., 2018). The decrease in traditional cigarette use among adolescents is a statement to the public health efforts on the national, state, and local levels through prevention, education, and policy developments.

After the success of cigarette use decreasing among adolescents and young adults, it is disturbing that the rates of alternative methods of tobacco delivery systems have emerged and increased dramatically, taking over as the most commonly used tobacco product (National Institute on Drug Abuse, 2018). The health effects of traditional tobacco products have been widely known for decades, however, the immediate and long-term health effects of electronic vapor products are still being researched. Regardless of the method of nicotine delivery, it is well documented that nicotine is one of the most addictive substances and is harmful to brain development in adolescents (CDC, 2018). Many chemicals are also known to be in electronic vapor products, including diacetyl, 2,3 prenanedione, and acetoin, which have been linked to bronchiolitis obliterans (popcorn lung) and other lung diseases (Printz, 2018). However, electronic vapor products, such as e-cigarettes, JUULs, vape pens, e-hookahs, and many others have been marketed as a safer alternative to traditional or

1

combustible tobacco products. With flavor categories such as candy or desserts, coffee, fruit, spice, or alcohol, it is not surprising that adolescents are drawn to the products. The high-tech features of some of the devices are also a draw for teens. Devices that resemble a USB drive or a pen can easily be concealed from parents or teachers and used when and wherever desired, which becomes a real problem for parents and schools in preventing the use of the products.

In May 2016, the Food and Drug Administration (FDA) issued a final rule that allows the agency the authority to have oversight over all tobacco products including electronic vapor products (American Lung Association [ALA], 2018). The FDA implemented policies to restrict the products to youth, prohibit certain flavors, and require warnings on packaging. However, youth-oriented flavors are still being sold from online stores, marketing of vapor products have just recently been removed on some social media outlets, but not all, and vape conventions are still occurring. It is clear that an ecological approach to decreasing the use of electronic vapor products among youth and adolescents is needed to curtail this epidemic. Parents need to be aware of the health effects from electronic vapor products, what they look like, and how exposed to the devices their children are so they can take steps to prevent their child from using electronic vapor products. Partnerships within communities need to be developed to implement policies prohibiting youth from purchasing the devices and pods, schools need to understand the best approach to preventing the use of the devices at school, and adolescents need to be educated on the dangers of using electronic vapor products. Through the ecological approach, eventually a denormalization process will happen and the rates of youth and adolescents using vapor products will decrease, just as it has with tradition smoking.

The current data related to youth and adolescents using electronic vapor products was primarily collected through the Youth Behavioral Risk Surveillance Survey (YBRSS), which is distributed in odd-numbered years by the CDC. Therefore, the data are from a national level and often collected from large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

2 Check all research activities that apply:

Audio, video, digital, or image recordings

Biohazards (e.g., rDNA, infectious agents, select agents, toxins)

- Biological sampling (other than blood)
- Blood drawing
- Class Protocol (or Program or Umbrella Protocol)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics
- Focus groups
- Internet or email data collection
- Materials that may be considered sensitive, offensive, threatening, or degrading
- Non-invasive medical procedures
- Observation of participants
- Oral history
- Placebo
- Record review
- Specimen research
- Surgical procedures
- Surveys, questionnaires, or interviews (one-on-one)
- ✓ Surveys, questionnaires, or interviews(group)
- Other

Describe the procedures and methods planned for carrying out the study. Make sure to include the following:

- Site selection,
- The procedures used to gain permission to carry out research at the selected sites(s),
- Data collection procedures, and
- An overview of the manner in which data will be analyzed.

Provide all information necessary for the IRB to be clear about all of the contact human participants will have with the project.

Design and setting:

The study will be a cross-sectional survey of 6th through 12th grade students and their parents at five rural school districts in Southwest Missouri. The survey will have an informed consent signed by the parents for the child. The child must bring the signed informed consent back to the school for the child to participate in the study. The students will also sign an assent to participate in the survey. Parents of the students will also be asked to participate in the survey and will have the option of either an electronic survey or a hard copy. Each school will determine how they want to distribute the survey to the parents and the students.

Sample:

- 3 The population for this study will be all 6th through 12th grade students whose parents returned the signed informed consent to the school and those students who also signed the assent form. Approximately 1433 students will have the opportunity of participating in the study. Parents or legal guardians of the students will also be surveyed related to their attitudes and knowledge regarding electronic vapor products. Approximately 1433 parents or legal guardians will have the opportunity to participate in the study.

Data Collection: The primary investigator will provide hard copy surveys to the five school districts in fall 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to parents at parent-teacher conferences and collect informed consents for the students from the parents. The primary investigator will send the Qualtrics link to the school counselor and a list of students who have a completed informed consent. The school counselor will email those students the Qualtrics link to complete while at school. The link will close by the end of the school day to insure the student does not take the survey outside of the school. All parent surveys will also be anonymous with non-identifiable demographic information.

Confidentiality and security: Participants will not be identified by name with hard copy surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored in a password protected computer also in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Attach tests, surveys, questionnaires, and other social-behavioral measurement tools, if applicable.

4

[Parent Vaping Survey_fall_Final.docx](#)

[Teen vaping survey_fall_FINAL.docx](#)

Attach documentation of site permission, if applicable.

5

[Email from Michelle Morris.docx](#)

Specify the participant population(s).

1

Check all that apply.

✓ Adults

✓ Children (<18 years of age) Adults

with decisional impairment Non-

English speaking

Student research pools (e.g. psychology)

Pregnant women or fetuses

Prisoners

Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program/class/umbrella protocols)

Specify the age(s) of the individuals who may participate in the research.

2

6th grade (11 years) to 12th grade (18 years) and parents or legal guardians

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

3

The participants are 6th through 12th grade students in five public middle schools and five public high schools in Polk County, MO as well as the parents or legal guardians of the students. They are included in the research to help determine the perceptions, and use of vaping among a local teen population. This information will allow health education program planners to better create interventions to prevent local students from initiating use of electronic vapor products. Parents of these students are included in the research to gain an understanding of the current level of knowledge among parents as well as what their perceptions are of teens using electronic vapor

products. This information will also help health education program planners develop relevant programs to educate parents related to electronic vapor products.

The survey will be distributed to El Dorado Springs, Strafford, and Niangua 6th through 12th grade summer school students and their parents in the summer of 2019. These students and parents will be recruited to conduct a pilot test of the survey so the potential of duplicating participants is eliminated.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval.

4

Approximately 1500 students and 1500 parents for Polk county schools in the fall of 2019, and 500 students and 500 parents for El Dorado Springs, Niangua, and Strafford schools during the summer of 2019

Describe what time commitment will be required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

5

The only interaction will be the completion of the survey which will take approximately 15-20 minutes for the students and 5-10 minutes for the parents.

Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

6

The primary investigator is partnering with the administrator of the Polk County Health Department on this research. The administrator has contacted the schools in Polk County and asked if the school would participate in the survey. Five middle schools in the county and five high schools in the county have confirmed that they would like to participate in the research. See attached email from Michelle Morris.

The primary investigator has been in contact with administrators at El Dorado Springs, Strafford, and Niangua schools. Niangua schools have given definite approval of implementing the survey during

the summer of 2019. The primary investigator is waiting on approval from both El Dorado Springs and Strafford schools.

Describe the recruitment process; including the setting in which recruitment will take place.

7

The primary investigator will provide hard copy surveys to the five school districts in fall 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in Oct. or the Qualtrics link be emailed to the students who have a completed informed consent. The primary investigator will also provide hard copy surveys or a Qualtrics link for the parents to complete the parent survey during parent-teacher conferences. All parent surveys will also be anonymous with non-identifiable demographic information. Parents will be asked to sign an informed consent for their student while at the parent-teacher conference and only students with a completed informed consent will receive the student survey.

The primary investigator will provide hard copy or electronic surveys to the school districts who chose to participate in the summer of 2019 to be distributed at their convenience to the students after getting informed consents from the students' parents. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in June. The primary investigator will also provide hard copy or electronic surveys for the parents to complete. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

Attach recruitment materials (ads, flyers, website postings, recruitment letters, and oral/written scripts), if applicable .

- 8 Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement, etc.)to participate in the research study?
-

Yes

✓ No

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence.

1

Consider the range of risks - physical, psychological, social, legal, and economic.

There are not risks to the students or parents beyond what is normally encountered in a regular day.

Discuss the steps that will be taken to minimize risks and the likelihood of harm.

Although there are no inherent risks in completing the survey, the following paragraph will be read to students before they take the survey or will be at the beginning of the Qualtrics survey if completed electronically.

2

Thank you for choosing to participate in this study. You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large “tank” devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and not looking at other students’ papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Describe the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.

3

There are no direct benefits to the students or parents in the study.

Discuss any potential indirect benefits to future subjects, science, and society.

4

The younger students and the parents may benefit later from the educational interventions developed from the information from the study. Other indirect benefits will be reducing the number of teens who start using electronic vapor products in Polk County through prevention programs created from results gained from this study. Other indirect benefits may be the development of cessation programs for teens and/or parents who use electronic vapor products. Through education and program development a shift in the social norm of using an electronic vapor product may change over time so fewer teens choose to start using the products as we've seen with traditional tobacco products.

Describe how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

5

The risks to the students and parents is minimal due to the questions being asked. The knowledge gained from the study is important to local program planners to understand the type of interventions that need to take place in their county. Currently, only national data has been collected related to teens and their perceptions, use, and addiction to electronic vapor products and that information has come from large urban school districts. Understanding what is happening at the local level allows for more direct and targeted interventions to take place. There also have not been any studies conducted to determine the current level of knowledge, perception, and use of electronic vapor products from parents as it relates to their child. This information will have a direct affect on the development of interventions that use an ecological approach, which is much more effective than just intervening only at the intrapersonal level.

From the list below, indicate how consent will be obtained for this study.

1

Check all that apply.

- ✓ Written/signed consent by the subject
- ✓ Written/signed consent (permission) for a minor by a Parent or Legal Guardian
- Written/signed consent by a Legally Authorized Representative (for adults incapable of consenting)
- Request for waiver of documentation of consent (verbal consent, anonymous surveys, etc.)
- Waiver of parental permission
- Waiver of consent (consent will not be obtained from subjects)

Describe the consent process including where and by whom the subjects will be approached, the plans to ensure the privacy of the subjects and the measures to ensure that subjects understand the nature of the study, its procedures, risks and benefits and that they freely grant their consent.

The primary investigator will ask parents to sign an informed consent for their child at the parent-teacher conferences so their child can then participate in the survey while at school. Only students who have a signed informed consent will be allowed to participate in the survey. The students who are allowed by their parents to participate will also sign an assent form before they participate in the survey.

2

Before each class participates in the survey, the students will be read information related to taking the survey, asking them to keep their information private and not to look at other student's papers or computers. The information will be as follows:

You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large "tank" devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and

not looking at other students' papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Attach all consent and assent documents here:

[ASSENT_Children_Under_18.doc](#)

[Parent Consent Form.docx](#)

[EVPOptIN.docx](#)

Missouri State University is committed to keeping data and information secure. Please review the Missouri Ste University [Information Security Policies](#). Discuss you project with the MSU Information Security Office or your College's IT support staff if you have questions about how to handle your data appropriately.

Statement of Principal Investigator Responsibility for Data

- 1 The principal investigator of this study is responsible for the storage, oversight, and disposal of all data associated with this study. Data will not be disseminated without the explicit approval of the principal investigator, and identifying information associated with the data will not be shared.
-

✓ By checking this box, all personnel associated with this study understand and agree to the Statement of Principal Investigator Responsibility for Data.

How will the data for this study be collected/stored?

2

Check all that apply.

✓ Electronic storage format
On paper

Describe where the data will be stored (e.g., paper forms, flash drives or removable media, desktop or laptop computer, server, research storage area network, external

source) and describe the plan to ensure the security and confidentiality of the records (e.g., locked office, locked file cabinet, password-protected computer or files, encrypted data files, database limited to coded data, master list stored in separate location).

At minimum, physical data should always be secured by lock and key when stored. Electronic data should be stored on University secure servers whenever possible (Office

- 3 *365 or other secure campus server). If data has to be stored off campus, the files should be encrypted and the device password protected. Additionally, any data to be shared outside the University network will require a SUDERS request be filed and approved. See <https://mis.missouristate.edu/Central/suders/create>*

Both electronic and paper forms will be used in the research.

Participants will not be identified by name with hard copy or online surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored on the primary investigator's campus computer in a secure campus server. The primary investigator's campus computer is also password protected in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Describe how data will be disposed of and when disposal will occur.

At minimum, Federal regulations require research records to be retained for at least 3

- 4 *years after the completion of the research (45 CFR 46). Research that involves identifiable health information is subject to HIPAA regulations, which require records to be retained for at least 6 years after a participant has signed an authorization. Finally, funded research projects may require longer retention periods, you may need to follow the sponsoring agency guidelines.*

All research records will be shredded and disposed of 3 years after the research study has concluded,

1 Please include any additional information about the study below.

Please include any additional documents that aren't covered within the application.

2

Modification Submission

Modification Summary

Please make changes to the original protocol sections below. In addition, provide a summary of the changes by completing the questions on this page.

To which of the following aspects of research does this modification request apply?

A.

Check all that apply.

Change in personnel

Research design

Risks to participants or others in relation to anticipated benefits

✓ Participant selection or recruitment process

Consent process and/or compensation Methods
for documenting consent

Change in supporting documentation or attachments

Potential willingness of research participants to continue to take part in this study

Monitoring of the data being collected

Privacy of the research participants and/or confidentiality of research participants' data

Other

Please provide a brief rationale for each of the changes being requested.

- B. Would like to expand the survey to college students in addition to the 6th through 12th grade students currently being surveyed. We will recruit students from the KIN 210 class to complete the survey.

Who is the Principal Investigator?

- 1 *This individual will be required to certify the protocol for submission and will be responsible for the overall project and **MUST be a faculty or staff member.***

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Who is the Primary Study Contact?

- 2 *This person, in addition to the Principal Investigator, will be included on all correspondence related to this project. This person may be the Principal Investigator or someone else (**faculty, staff, or student**).*

Name: Stacy Goddard

Organization: Kinesiology

Address: 901 S National Ave , Springfield, MO 65897-0027

Phone: 417-836-8572

Email: sgoddard@missouristate.edu

Will there be any Co-Principal Investigators participating in this study?

3. *Co-Principal Investigators will also be required to certify the protocol for submission and share overall responsibility with the Principal Investigator for the study. Co-Principal Investigators **MUST be faculty or staff members.***

Yes

✓ No

Will there be any other individuals participating with the investigation?

4

These individuals will be participating as part of the research team, but will not need to certify the protocol submissions, or be included in any correspondence regarding the study. Typically these individuals will be students or individuals from other institutions. Investigators may be faculty, staff, students, or unaffiliated individuals.

✓ Yes

Select the Investigator(s)

No

What is the full title of the research protocol?

1

Adolescents' and Parents' Perceptions and Behaviors Related to Electronic Vapor Products

Abstract/Summary

Please provide a brief description of the project.

2

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). Adolescents have begun using electronic vapor products at an alarming rate while the research related to the health effects of the products is lagging behind. The current data related to youth and adolescents using electronic vapor products has primarily been collected through national surveys that mainly focus on large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

Are you requesting Single IRB Review

3

Single IRB Review is applicable to a study that is being reviewed by another Institution's IRB, in which you wish to rely on the external IRB for review, approval, and oversight.

Yes

✓ No

Does the study require review and oversight of the IRB?

4

Regardless of how these questions are answered, the determination of IRB review and oversight is made by the IRB and this study will still need to be submitted for preliminary review.

Is this study a systematic investigation, following a predetermined plan, for looking at a particular issue, testing a hypothesis or research question, or developing a new theory that includes any of the following:

- 4A
- Collection or analysis of quantitative or qualitative data
 - Collection of data using surveys, testing or evaluation procedures, interviews, or focus groups
 - Collection of data using experimental designs such as clinical trials
 - Observation of individual or group behavior
-

✓ Yes
No

Will this study contribute to generalizable knowledge, in that the purpose or intent of the project is to test or to develop scientific theories or hypotheses, or to draw conclusions that are intended to be applicable and/or shared beyond the populations or situations being studied? This may include one or more of the following:

- 4B
- Presentation of the data at meetings, conferences, seminars, poster presentations, etc.
 - The knowledge contributes to an already established body of knowledge Other investigators, scholars, and practitioners may benefit from this knowledge
 - Publications including journals, papers, dissertations, and theses
-

✓ Yes
No

4C Will this study require obtaining information or biospecimens, through intervention or interaction with an individual that will be used, studied, or analyzed by the investigative team?

☒ Yes
☐ No

Will you be requesting an Exempt Review for this study?

5

In order to qualify for review via exempt procedures, the research must not be greater than minimal risk and must fall into at least one of the exempt categories defined by federal regulations.

☐ Yes
☒ No

6 Is this study receiving internal or external funding?

☐ Yes
☒ No

Does this study contain protected health information (PHI)?

7

PHI is any information in a medical record or designated record set that can be used to identify an individual and that was created, used, or disclosed in the course of providing a health care service, such as a diagnosis or treatment.

Yes

✓ No

8 Has all IRB Human Research training been taken through CITI under Missouri State University?

Yes

✓ No

Training Certificates

8A *Please upload all training certificates taken outside of CITI, or CITI certificates completed through another institution.*

[Sheppard - CITI Program - Feb 2023.pdf](#)

[Michelle CITI training.pdf](#)

Describe the proposed project in a manner that allows the IRB to gain a sense of the project including:

- The research questions and objectives,
- Key background literature (supportive and contradictory) with references, and The manner in which the proposed project will improve the understanding of the chosen topic.

Research Questions

1. What are the factors that predict the use of electronic vapor products?
2. What is the relationship between frequency of use of electronic vapor products and strength of nicotine dependence.
3. What is the relationship between perceptions of health risk and parental discussion of electronic vapor products?

Vaping among teens has been officially classified as an epidemic by the U.S. Surgeon General (Stein, 2018). This report was in response to the dramatic increase in use of electronic vapor products in the last several years. For example, use of electronic cigarettes increased among middle school students from 0.6% in 2011 to 4.9% in 2018 and among high school students, the prevalence increased from 1.5% in 2011 to 20.8% in 2018 (Kann et al., 2018). The increase in electronic vapor product use among teens came at the same time as a decrease in traditional tobacco use. From 2011 to 2017, 2.1% of middle school students reported smoking traditional cigarettes, which was a decrease from 4.3% in 2011 (Kann et al., 2018). Likewise, in 2017, 7.6% of high school students reported smoking cigarettes in the past 30 days, which was also a decrease from 15.8% in 2011 (Kann et al., 2018). The decrease in traditional cigarette use among adolescents is a statement to the public health efforts on the national, state, and local levels through prevention, education, and policy developments.

After the success of cigarette use decreasing among adolescents and young adults, it is disturbing that the rates of alternative methods of tobacco delivery systems have emerged and increased dramatically, taking over as the most commonly used tobacco product (National Institute on Drug Abuse, 2018). The health effects of traditional tobacco products have been widely known for decades, however, the immediate and long-term health effects of electronic vapor products are still being researched. Regardless of the method of nicotine delivery, it is well documented that nicotine is one of the most addictive substances and is harmful to brain development in adolescents (CDC, 2018). Many chemicals are also known to be in electronic vapor products, including diacetyl, 2,3 prenanedione, and acetoin, which have been linked to bronchiolitis obliterans (popcorn lung) and other lung diseases (Printz, 2018). However, electronic vapor products, such as e-cigarettes, JUULs, vape pens, e-hookahs, and many others have been marketed as a safer alternative to traditional or

1

combustible tobacco products. With flavor categories such as candy or desserts, coffee, fruit, spice, or alcohol, it is not surprising that adolescents are drawn to the products. The high-tech features of some of the devices are also a draw for teens. Devices that resemble a USB drive or a pen can easily be concealed from parents or teachers and used when and wherever desired, which becomes a real problem for parents and schools in preventing the use of the products.

In May 2016, the Food and Drug Administration (FDA) issued a final rule that allows the agency the authority to have oversight over all tobacco products including electronic vapor products (American Lung Association [ALA], 2018). The FDA implemented policies to restrict the products to youth, prohibit certain flavors, and require warnings on packaging. However, youth-oriented flavors are still being sold from online stores, marketing of vapor products have just recently been removed on some social media outlets, but not all, and vape conventions are still occurring. It is clear that an ecological approach to decreasing the use of electronic vapor products among youth and adolescents is needed to curtail this epidemic. Parents need to be aware of the health effects from electronic vapor products, what they look like, and how exposed to the devices their children are so they can take steps to prevent their child from using electronic vapor products. Partnerships within communities need to be developed to implement policies prohibiting youth from purchasing the devices and pods, schools need to understand the best approach to preventing the use of the devices at school, and adolescents need to be educated on the dangers of using electronic vapor products. Through the ecological approach, eventually a denormalization process will happen and the rates of youth and adolescents using vapor products will decrease, just as it has with tradition smoking.

The current data related to youth and adolescents using electronic vapor products was primarily collected through the Youth Behavioral Risk Surveillance Survey (YBRSS), which is distributed in odd-numbered years by the CDC. Therefore, the data are from a national level and often collected from large urban school districts. Although this gives an understanding of what is occurring with certain risk behaviors nationally, it does not allow program planners to understand the risk behavior problems at the local level. Conducting a survey in local school districts related to the use of electronic vapor products in middle and high school students will give program planners a better understanding of the problem and how to begin to address the problem. Collecting data from parents of middle and high school students will also allow program planners to determine the best method to help parents understand the issue and guide them in their efforts to keep their children from using the electronic vapor products.

2 Check all research activities that apply:

Audio, video, digital, or image recordings

Biohazards (e.g., rDNA, infectious agents, select agents, toxins)

- Biological sampling (other than blood)
- Blood drawing
- Class Protocol (or Program or Umbrella Protocol)
- Data, not publicly available
- Data, publicly available
- Deception
- Devices
- Diet, exercise, or sleep modifications
- Drugs or biologics
- Focus groups
- Internet or email data collection
- Materials that may be considered sensitive, offensive, threatening, or degrading
- Non-invasive medical procedures
- Observation of participants
- Oral history
- Placebo
- Record review
- Specimen research
- Surgical procedures
- Surveys, questionnaires, or interviews (one-on-one)
- ✓ Surveys, questionnaires, or interviews(group)
- Other

Describe the procedures and methods planned for carrying out the study. Make sure to include the following:

- Site selection,
- The procedures used to gain permission to carry out research at the selected sites(s),
- Data collection procedures, and
- An overview of the manner in which data will be analyzed.

Provide all information necessary for the IRB to be clear about all of the contact human participants will have with the project.

Design and setting:

The study will be a cross-sectional survey of 6th through 12th grade students and their parents at five rural school districts in Southwest Missouri. The survey will have an informed consent signed by the parents for the child. The child must bring the signed informed consent back to the school for the child to participate in the study. The students will also sign an assent to participate in the survey. Parents of the students will also be asked to participate in the survey and will have the option of either an electronic survey or a hard copy. Each school will determine how they want to distribute the survey to the parents and the students.

Sample:

- 3 The population for this study will be all 6th through 12th grade students whose parents returned the signed informed consent to the school and those students who also signed the assent form. Approximately 1433 students will have the opportunity of participating in the study. Parents or legal guardians of the students will also be surveyed related to their attitudes and knowledge regarding electronic vapor products. Approximately 1433 parents or legal guardians will have the opportunity to participate in the study.

Data Collection: The primary investigator will provide hard copy surveys to the five school districts in fall 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to parents at parent-teacher conferences and collect informed consents for the students from the parents. The primary investigator will send the Qualtrics link to the school counselor and a list of students who have a completed informed consent. The school counselor will email those students the Qualtrics link to complete while at school. The link will close by the end of the school day to insure the student does not take the survey outside of the school. All parent surveys will also be anonymous with non-identifiable demographic information.

Confidentiality and security: Participants will not be identified by name with hard copy surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored in a password protected computer also in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Attach tests, surveys, questionnaires, and other social-behavioral measurement tools, if applicable.

4

[Parent Vaping Survey_fall_Final.docx](#)

[Teen vaping survey_fall_FINAL.docx](#)

Attach documentation of site permission, if applicable.

5

[Email from Michelle Morris.docx](#)

Specify the participant population(s).

1

Check all that apply.

- ✓ Adults
- ✓ Children (<18 years of age) Adults
 - with decisional impairment Non-
 - English speaking
 - Student research pools (e.g. psychology)
 - Pregnant women or fetuses
 - Prisoners
 - Unknown (e.g., secondary use of data/specimens, non-targeted surveys, program/class/umbrella protocols)

Specify the age(s) of the individuals who may participate in the research.

2

6th grade (11 years) to 12th grade (18 years) and parents or legal guardians and KIN 210 students

Describe the characteristics of the proposed participants, and explain how the nature of the research requires/justifies their inclusion.

The participants are 6th through 12th grade students in five public middle schools and five public high schools in Polk County, MO as well as the parents or legal guardians of the students. They are included in the research to help determine the perceptions, and use of vaping among a local teen population. This information will allow health education program planners to better create interventions to prevent local students from initiating use of electronic vapor products. Parents of these students are included in the research to gain an understanding of the current level of

3

knowledge among parents as well as what their perceptions are of teens using electronic vapor

products. This information will also help health education program planners develop relevant programs to educate parents related to electronic vapor products.

The survey will be distributed to El Dorado Springs, Strafford, and Niangua 6th through 12th grade summer school students and their parents in the summer of 2019. These students and parents will be recruited to conduct a pilot test of the survey so the potential of duplicating participants is eliminated.

College students are a large part of the vaping epidemic and assessing their knowledge, perceptions, and behaviors will be important to see if any of these components change from the middle and high school age up to the college age.

Provide the total number of participants (or number of participant records, specimens, etc.) for whom you are seeking IRB approval.

4

Approximately 1500 students and 1500 parents for Polk county schools in the fall of 2019, and 500 students and 500 parents for El Dorado Springs, Niangua, and Strafford schools during the summer of 2019. Approximately 200 students in the KIN 210 classes

Describe what time commitment will be required from each participant, including individual interactions, total time commitment, and long-term follow-up, if any.

5

The only interaction will be the completion of the survey which will take approximately 15-20 minutes for the students and 5-10 minutes for the parents.

Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.

6

The primary investigator is partnering with the administrator of the Polk County Health Department on this research. The administrator has contacted the schools in Polk County and asked if the school would participate in the survey. Five middle schools in the county and five high schools in the county have confirmed that they would like to participate in the research. See attached email from

Michelle Morris.

The primary investigator has been in contact with administrators at El Dorado Springs, Strafford, and Niangua schools. Niangua schools have given definite approval of implementing the survey during the summer of 2019. The primary investigator is waiting on approval from both El Dorado Springs and Strafford schools.

The primary investigator has been given permission from the coordinator of the KIN 210 class to survey the students.

Describe the recruitment process; including the setting in which recruitment will take place.

The primary investigator will provide hard copy surveys to the five school districts in fall 2019 to be distributed at their convenience to the students. The schools will also have the ability to have students with Chrome books complete the survey online, but each student will only complete one survey, either hard copy or electronic. All surveys will be anonymous with non-identifying demographic information. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in Oct. or the Qualtrics link be emailed to the students who have a completed informed consent. The primary investigator will also provide hard copy surveys or a Qualtrics link for the parents to complete the parent survey during parent-teacher conferences. All parent surveys will also be anonymous with non-identifiable demographic information. Parents will be asked to sign an informed consent for their student while at the parent-teacher conference and only students with a

7

completed informed consent will receive the student survey.

The primary investigator will provide hard copy or electronic surveys to the school districts who chose to participate in the summer of 2019 to be distributed at their convenience to the students after getting informed consents from the students' parents. All surveys will be anonymous with non-identifying demographic information. Specific questions will create a unique identifier that will link a student's survey responses to his or her parent's survey to allow for analyzing information between parent and child. However, the unique IDs will be anonymous. The suggested protocol will be for the primary investigator and other investigators to distribute the surveys to students on one day at each school during a two-week period in June. The primary investigator will also provide hard copy or electronic surveys for the parents to complete. The schools that request electronic copies for the parents will email the survey to the parents from their email distribution lists. All parent surveys will also be anonymous with non-identifiable demographic information.

The primary investigator will give the Qualtrics survey link to the KIN 210 lab instructors who will email the link to their students and then will have the students pull up the survey during class time and have the students who choose to participate complete the survey.

Attach recruitment materials (ads, flyers, website postings, recruitment letters, and oral/written scripts), if applicable .

- 8 Will participants receive compensation or other incentives (e.g., free services, cash payments, gift certificates, parking, classroom credit, travel reimbursement, etc.) to participate in the research study?
-

Yes

✓ No

Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. Discuss severity and likelihood of occurrence.

1

Consider the range of risks - physical, psychological, social, legal, and economic.

There are not risks to the students or parents beyond what is normally encountered in a regular day.

Discuss the steps that will be taken to minimize risks and the likelihood of harm.

Although there are no inherent risks in completing the survey, the following paragraph will be read to students before they take the survey or will be at the beginning of the Qualtrics survey if completed electronically.

2

Thank you for choosing to participate in this study. You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large “tank” devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and not looking at other students’ papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Describe the potential benefits that participants may expect as a result of this research study. State if there are no direct benefits to individual participants.

3

There are no direct benefits to the students or parents in the study.

Discuss any potential indirect benefits to future subjects, science, and society.

4

The younger students and the parents may benefit later from the educational interventions developed from the information from the study. Other indirect benefits will be reducing the number of teens who start using electronic vapor products in Polk County through prevention programs created from results gained from this study. Other indirect benefits may be the development of cessation programs for teens and/or parents who use electronic vapor products. Through education and program development a shift in the social norm of using an electronic vapor product may change over time so fewer teens choose to start using the products as we've seen with traditional tobacco products.

Describe how risks to participants are reasonable when compared to the anticipated benefits to participants (if any) and the importance of the knowledge that may reasonably be expected to result.

5

The risks to the students and parents is minimal due to the questions being asked. The knowledge gained from the study is important to local program planners to understand the type of interventions that need to take place in their county. Currently, only national data has been collected related to teens and their perceptions, use, and addiction to electronic vapor products and that information has come from large urban school districts. Understanding what is happening at the local level allows for more direct and targeted interventions to take place. There also have not been any studies conducted to determine the current level of knowledge, perception, and use of electronic vapor products from parents as it relates to their child. This information will have a direct affect on the development of interventions that use an ecological approach, which is much more effective than just intervening only at the intrapersonal level.

From the list below, indicate how consent will be obtained for this study.

1

Check all that apply.

- ✓ Written/signed consent by the subject
- ✓ Written/signed consent (permission) for a minor by a Parent or Legal Guardian
- Written/signed consent by a Legally Authorized Representative (for adults incapable of consenting)
- Request for waiver of documentation of consent (verbal consent, anonymous surveys, etc.)
- Waiver of parental permission
- Waiver of consent (consent will not be obtained from subjects)

Describe the consent process including where and by whom the subjects will be approached, the plans to ensure the privacy of the subjects and the measures to ensure that subjects understand the nature of the study, its procedures, risks and benefits and that they freely grant their consent.

The primary investigator will ask parents to sign an informed consent for their child at the parent-teacher conferences so their child can then participate in the survey while at school. Only students who have a signed informed consent will be allowed to participate in the survey. The students who are allowed by their parents to participate will also sign an assent form before they participate in the survey.

2

Before each class participates in the survey, the students will be read information related to taking the survey, asking them to keep their information private and not to look at other student's papers or computers. The information will be as follows:

You are being asked to participate in a survey related to electronic vapor products, which refers to any type of non-combustible tobacco product as well as electronic devices that vaporize a liquid such as e-cigarettes, JUULs, vape pens, small or large "tank" devices, hookahs, or any other similar device that may or may not contain nicotine. All of your answers will be kept confidential and your survey will be anonymous meaning once you complete it, we will not know who completed each survey. This information will help us understand teen views and use of electronic vapor products. This information may be used to develop educational, prevention, and cessation programs for teens in the future. Please complete the survey as honestly as possible, keeping your answers private and

not looking at other students' papers or computer. You may choose to quit taking the survey at any point, but your participation is appreciated. The survey will take approximately 15-20 minutes to complete.

Attach all consent and assent documents here:

[ASSENT_Children_Under_18.doc](#)

[Parent Consent Form.docx](#)

[EVPOptIN.docx](#)

[Student Consent Form.docx](#)

Missouri State University is committed to keeping data and information secure. Please review the Missouri Ste University [Information Security Policies](#). Discuss you project with the MSU Information Security Office or your College's IT support staff if you have questions about how to handle your data appropriately.

Statement of Principal Investigator Responsibility for Data

- 1 The principal investigator of this study is responsible for the storage, oversight, and disposal of all data associated with this study. Data will not be disseminated without the explicit approval of the principal investigator, and identifying information associated with the data will not be shared.
-

✓ By checking this box, all personnel associated with this study understand and agree to the Statement of Principal Investigator Responsibility for Data.

How will the data for this study be collected/stored?

2

Check all that apply.

✓ Electronic storage format
On paper

Describe where the data will be stored (e.g., paper forms, flash drives or removable media, desktop or laptop computer, server, research storage area network, external

source) and describe the plan to ensure the security and confidentiality of the records (e.g., locked office, locked file cabinet, password-protected computer or files, encrypted data files, database limited to coded data, master list stored in separate location).

At minimum, physical data should always be secured by lock and key when stored. Electronic data should be stored on University secure servers whenever possible (Office

- 3 *365 or other secure campus server). If data has to be stored off campus, the file should be encrypted and the device password protected. Additionally, any data to be shared outside the University network will require a SUDERS request be filed and approved. See <https://mis.missouristate.edu/Central/suders/create>*

Both electronic and paper forms will be used in the research.

Participants will not be identified by name with hard copy or online surveys and only basic demographic information will be collected. Electronic surveys will be administered through Qualtrics, which provides an SSL encryption feature, which means that data is protected as it is transmitted over a secure, encrypted connection. Finally, all hard copy data will be kept in a secure, locked file cabinet in the primary investigator's office, all electronic data will be stored on the primary investigator's campus computer in a secure campus server. The primary investigator's campus computer is also password protected in the primary investigator's locked office. The researchers are the only persons who will have access to the data.

Describe how data will be disposed of and when disposal will occur.

At minimum, Federal regulations require research records to be retained for at least 3

- 4 *years after the completion of the research (45 CFR 46). Research that involves identifiable health information is subject to HIPAA regulations, which require records to be retained for at least 6 years after a participant has signed an authorization. Finally, funded research projects may require longer retention periods, you may need to follow the sponsoring agency guidelines.*

All research records will be shredded and disposed of 3 years after the research study has concluded,

1 Please include any additional information about the study below.

Please include any additional documents that aren't covered within the application.

2

Renewal Submission

1

This Renewal Request is intended to continue your previously approved study for an additional period of time, if approved. Any modifications to the research study must be submitted via a Modification Request.

1A. Indicate the current status of the research:

Research has not yet started at any location

✓ Research is open to accrual of new participants (for specimen/data only research, the collection of new specimens or records is ongoing)

Closed to accrual: accrual is temporarily on hold

Closed to accrual: clinical interventions, surveys, or similar participant interactions are continuing.

Closed to accrual: remaining activity is limited to collection of participant long-term follow-up data.

Closed to accrual: remaining activities limited to analysis of data/specimens already collected.

Other

Please provide a summary of your progress with this research to date, including any interim findings since the last review.

- 2A. I am collecting data next week (Feb. 17-21) with the KIN 210 courses and then will be done with the data collection part of the research. The data from the Fall '19 semester was good for the thesis project, but I need a bigger sample size to publish the results. Therefore I am using the current semester's KIN 210 students to collect more data.

- 2B. Have there been any significant problems or issues with the research since the last review?

Yes

✓ No

Have there been any changes in the research, new risk information, or any other new information since your last review which would alter the following presumptions about the research?

- 2C.
- Risks to participants in this research project are minimized.
 - Risks to participants are reasonable in relation the the anticipated benefits to the participant or importance of the generalizable knowledge expected as a result of this research.
 - The selection of participants, specimens or data is equitable.
 - Provisions for obtaining and documenting informed consent are adequate. Appropriate data monitoring is in place to ensure safety of participants.
 - Appropriate safeguards are in place to protect participants' privacy and confidentiality.
 - Appropriate safeguards are in place to protect participants who may be vulnerable to coercion or undue influence.

Yes

✓ No

2D.

Have all members of the research team received and remained up-to-date on the required training on Human Subjects Protection?

Note: Any new members to the research team must be added via a Modification Request.

✓ Yes

No

Appendix B: m-HOOKED ON NICOTINE CHECKLIST(m-HONC)

These next few questions will ask about your use of vape products.

	Extremely	Very	Moderately	Slightly	Not at All
If you have ever tried to quit, how hard was it to quit vaping? (Skip if you've never tried to quit.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How likely are you to continue to vape because it is too hard to quit?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How addicted do you feel to vaping?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How strong are your cravings to vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How strongly do you feel you really need to vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How hard is it to keep from vaping in places where you are not supposed to, like school?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When you haven't used a vape for a while...OR When you tried to stop vaping...					
How hard was it to concentrate because you could not vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How irritable did you feel because you could not vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How strong of a need did you have to vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How nervous, restless or anxious did you feel because you could not vape?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>