Study Title: A Needs Survey of Urban Day Shelter Users and Preliminary Evaluation of a Tobacco Harm Reduction Intervention: The Exchange Project

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RESEARCH PROTOCOL OUTLINE

Title of Project: **A Needs Survey of Urban Day Shelter Users and Preliminary Evaluation of a Tobacco Harm Reduction Intervention: The Exchange Project**

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Abstract

Switching from combustible cigarettes to e-cigarette use may be a practical harm reduction strategy for vulnerable groups with a high smoking prevalence and a low likelihood of cessation. There is substantial evidence that offering financial incentives for smoking abstinence is an effective approach for promoting smoking cessation in a variety of challenging populations, nevertheless the majority are still not able to quit. The combination of offering financial incentives to incentivize combustible cigarette abstinence, while offering e-cigarettes as an alternative is a novel and potentially powerful harm reduction approach that may lead to reduced cigarette consumption in a population that is unlikely to quit smoking. The proposed study will provide initial information about the feasibility of using this harm reduction strategy to reduce cigarette consumption among homeless adults. The aims of the proposed study are to: 1) assess the characteristics and needs of Homeless Alliance Day Shelter users (up to 1000 adults), 2) characterize tobacco and e-cigarette use patterns, tobacco history, and past cessation attempts among individuals accessing services at the Homeless Alliance Day Shelter, and 3) assess interest in tobacco cessation and tobacco harm reduction intervention approaches. A sub-study (*N* = 60) will 4) characterize reductions in cigarette smoking, complete cigarette abstinence, e-cigarette use, and dual use of combustible cigarettes and e-cigarettes among Homeless Alliance Day Shelter guests following the provision of: an e-cigarette device and supplies (pods, device charger) or e-cigarette device + financial incentives for combustible cigarette abstinence.

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A. Specific Aims

The aims of the proposed study are to: 1) assess characteristics and needs of up to 1000 adult males and females who receive services at the Oklahoma City Homeless Alliance Day Shelter, 2) characterize tobacco and e-cigarette use patterns, tobacco history, and past cessation attempts among individuals using services at the Homeless Alliance Day Shelter, and 3) assess interest in tobacco cessation and tobacco harm reduction intervention approaches. A sub-study (randomized controlled trial; *N* = 60) will: 4) complete cigarette abstinence, e-cigarette use, and dual use of combustible cigarettes and e-cigarettes among Homeless Alliance Day Shelter guests following the provision of an e-cigarette device with nicotine pods and the ability to earn financial incentives for abstaining from combustible cigarettes. Sub-study participants will be randomly assigned to: 1) the provision of an e-cigarette device and supplies/pods through 4 weeks post-switch along with directions to switch over from combustible cigarettes to e-cigarettes exclusively, or 2) the combination of an e-cigarette device and supplies through 4 weeks post-switch and financial rewards to incentivize combustible cigarette abstinence, which is based on a previously developed incentive schedule for socioeconomically disadvantaged and homeless adults.[1-3] In both groups, cigarette smoking will be monitored over an 8-week period to characterize reductions in cigarette smoking, cigarette abstinence, dual use (combustible cigarettes and e-cigarettes) and rates of exclusive e-cigarette use (i.e., switching). It is anticipated that individuals who are provided with an e-cigarette device and supplies and are also incentivized for combustible cigarette abstinence will show greater reductions in cigarette smoking and be more likely to quit combustible cigarettes and switch to exclusive e-cigarette use. The long-term objectives of the survey are to inform improvements to the services available to Day Shelter users and to identify strategies to help homeless adults quit smoking or reduce harm associated with smoking.

B. Background and Significance

Poor health is commonplace among homeless adults, who suffer mortality rates at least 3 times greater than adults in the general population.[4-7] Although smoking rates have declined to 13.9% among adults living at or above the poverty threshold in the U.S., the prevalence of smoking is 26.1% among those living in poverty,[8] and at least 70% among homeless adults.[9,10] Numerous studies have shown that lower socioeconomic status (SES) is associated with a reduced likelihood of smoking cessation,[11-17] despite a similar number of cessation attempts between individuals of lower and higher SES.[15] Not surprisingly, socioeconomic disadvantage is linked with greater tobacco-related cancer incidence and mortality risk.[18] Although standard cessation approaches are helpful for many,[19] alternative strategies may benefit those who are unable to quit following traditional evidence-based treatment recommendations. Switching from combustible cigarette smoking to e-cigarettes exclusively may be a practical harm reduction strategy for some,[20] especially vulnerable groups with a high smoking prevalence and a reduced likelihood of cessation. The possibility of

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utilizing e-cigarettes as a harm reduction tool has become more feasible based on research demonstrating that e-cigarettes are associated with far fewer harmful exposures than cigarette smoking.[21-23] Nevertheless, serious concern developed over the summer/fall of 2019 about the sudden and rising number of e-cigarette and vaping-related lung injury (EVALI) cases. Recent information indicates that EVALI was primarily associated with THC-containing vaping products acquired from informal sources,[24] which contained the product additive - vitamin E acetate.[25-27] Since September 2019, EVALI hospital admissions have sharply declined[28] possibly due to increased public awareness of the risks associated with THC-containing e-cigarette use, removal of vitamin E acetate from vaping products, and law enforcement actions taken to reduce the availability of illicit products.[29,30] In February 2020, the Centers for Disease Control and Prevention (CDC) stopped collecting data on EVALI following the identification of the cause of EVALI and the decline in cases.[29]

There is substantial evidence that offering financial incentives for cigarette abstinence is an effective approach for promoting smoking cessation in a variety of challenging populations.[31] Dr. Kendzor's published work[1,2,32] as well as findings from her ongoing NIH-funded trial (IRB protocol #6260),[33,34] indicate that offering small escalating financial incentives for smoking abstinence dramatically increases cessation rates among socioeconomically disadvantaged smokers when incentives are included as an adjunct to standard treatment. The combination of offering both financial incentives for smoking abstinence and e-cigarettes as an alternative to smoking is a novel and potentially powerful harm reduction approach for those who are less likely to quit smoking. The proposed study will provide information about the feasibility of using alternative intervention strategies for socioeconomically disadvantaged and homeless adults who continue to smoke. E-cigarettes, alone or in combination with smoking financial incentives for cigarette abstinence, may be incorporated into existing tobacco cessation programs to decrease the use of combustible cigarettes among socioeconomically disadvantaged smokers. New and innovative approaches are needed to address worsening tobacco-related health disparities.

C. Preliminary Studies/Progress Report

Darla Kendzor earned her Ph.D. in Clinical Psychology from Louisiana State University in 2007. She is currently an Associate Professor in the Department of Family and Preventive Medicine, and a member of the Cancer Prevention and Control Program of the Stephenson Cancer Center Cancer. Dr. Kendzor leads the Tobacco Treatment Research Program (TTRP),[35,36] which offers free counseling and pharmacotherapy to adults from campus and the community while collecting data relevant to the process of smoking cessation and facilitating recruitment into research studies (IRB protocol #6951). She has published extensively in the areas of tobacco cessation interventions, behavioral medicine, cancer prevention, and health disparities, and she has a history of external funding from the American Cancer Society (ACS) and the National Cancer Institute (NCI). Notably, Dr. Kendzor previously completed a randomized

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controlled trial (RCT) to evaluate the feasibility and short-term effectiveness of offering small financial incentives (gift cards) for biochemically verified abstinence as an adjunct to the tobacco cessation program offered at the Dallas County safety net hospital.[1] Dr. Kendzor also completed an NCI-funded follow-up RCT to evaluate the longer-term impact of an adjunctive, low-cost intervention offering small financial incentives (relative to standard care) on smoking abstinence rates among socioeconomically disadvantaged individuals participating in a clinic-based tobacco cessation program.[33] She is currently conducting an NCI-funded trial of an automated, mobile incentives-based smoking cessation intervention for low-income adults.[37] Notably, Dr. Kendzor has a history of published research directly relevant to tobacco cessation interventions, and especially within socioeconomically disadvantaged populations.[2,12,14,38-46] She has also conducted tobacco and health-related research within homeless populations specifically.[47-52] Dr. Ahluwalia provides expertise related to e-cigarettes and switching from combustible cigarettes to e-cigarettes.[21,53-61] Dr. Businelle is a long-time collaborator of Dr. Kendzor, and provides additional expertise related to tobacco cessation intervention in socioeconomically disadvantaged[14,62] and homeless populations.[2,63] Dr. Frank-Pearce provides biostatistics expertise, and Dr. Alexander is a collaborator and trainee of Dr. Kendzor with expertise in tobacco cessation interventions and health disparities.

D. Research Design and Methods

Overview. The current protocol includes a parent survey study, and an intervention sub-study. The parent survey study will assess the characteristics and needs of Homeless Alliance Day Shelter users (up to 1000 adults), 2) characterize tobacco and e-cigarette use patterns, tobacco history, and past cessation attempts among individuals accessing services at the Homeless Alliance Day Shelter, and 3) assess interest in tobacco cessation and harm reduction intervention approaches. Based on responses to screening items assessing eligibility criteria, participants will be identified as eligible for the sub-study. The sub-study (*N* = 60) will 4) characterize reductions in cigarette smoking, smoking abstinence, e-cigarette dual use, and e-cigarette use/switching following randomization to: 1) an e-cigarette device and supplies (device charger, pods) for 4 weeks, or 2) e-cigarette and supplies for 4 weeks + financial incentives for combustible cigarette abstinence among Homeless Alliance Day Shelter guests. Participants will be followed through 8 weeks post-switch date to determine whether they continue to use e-cigarettes when the supplies are no longer provided. Both the parent survey study and intervention sub-study will provide data related to tobacco use, which will be used to support future grant funding applications. Both components of the study will take place at the Homeless Alliance Day Shelter.

Survey Study

The current study is a one-time survey of up to 1000 predominantly homeless adults accessing services at the Homeless Alliance Day Shelter (1729 N.W. 3rd

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Street, Oklahoma City, OK 73106). A convenience sample of unique shelter guests will be surveyed on several days each month over a one-year period, to understand the needs of users in light of seasonal and financial factors that vary over the days of the month (e.g., government paychecks) and months of the year (e.g., seasonal variations in temperature/weather). Study staff will be stationed near the entrance of the day shelter to provide information about the study and answer questions. Day Shelter guests who are present at the time when study staff are also present will be approached for participation in the study (or they may approach us). Study staff will plan to enroll unique survey participants (i.e., participants may not participate in the survey twice).

(Survey Study; pre-COVID – Before March 2020)
Those enrolled will complete a 30-minute survey on a tablet computer at the day shelter. Study staff may read the survey questions to the participant and assist them in selecting answers on the tablet computer. Participants may be provided with reading glasses as needed. Participants will provide information on many factors related to homelessness including sociodemographic information, stress and discrimination, substance use, mental health history, social support, and criminal justice involvement (see survey questionnaire for a full list of questions asked during the survey study). Participants will be provided with a $10 gift card.

Sub-Study.
Overview. The sub-study will examine the feasibility and preliminary efficacy of providing financial incentives for combustible cigarette abstinence in combination with switching to e-cigarettes among 60 socioeconomically disadvantaged Homeless Alliance day shelter users. A total of 60 adults who access the day shelter will be recruited to participate in the sub-study. Participants will be randomly assigned to one of two groups and followed weekly from 1 week prior to switching through 4 weeks after switching, with a final 8-week post-switch follow-up. The intervention groups are 1) switching to e-cigarettes (EC), or 2) small financial incentives for cigarette abstinence + switching to e-cigarettes (FI + EC). Payments will be made via Greenphire clincard, which is similar to a debit card.The primary outcome will be carbon monoxide (CO)-verified combustible cigarette abstinence (CO) at 4- and 8-weeks post-switch date. Combustible cigarette reduction, EC use/switching, and dual use (cigarettes and ECs) will also be examined.

Intervention Groups. All participants will have the opportunity to earn $20 for completing study assessments at visits 2 through 7 and $50 for completing visit 8 (see Table 1).

Financial Incentives + E-Cigarettes (FI + EC). At baseline (1-week pre-switch), participants assigned to this group will be provided with an e-cigarette[64] device and they will be offered 7 pods to try. Participants will be encouraged to practice using the device over the subsequent week (before they switch to exclusive use). Participants will be advised to completely switch from combustible cigarettes to

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the e-cigarette device one week after the baseline visit. On the switch date, they will be supplied with refill cartridges in the flavor(s) of their choice and based on their pre-switch smoking level. One pod ≈ 200 puffs and provides the amount of nicotine in ≈ 1 pack of cigarettes. Thus, someone who smokes a pack of cigarettes each day may be expected to use about 1 pod per day.

Participants in this group can also earn financial incentives for combustible cigarette abstinence. Financial incentives will be earned based on self-reported cigarette abstinence and carbon monoxide readings. Beginning with a $20 payment for self-reporting exclusive e-cigarette use during the past 24 hours along with a CO reading of ≤8 ppm on the specified switch day (i.e., one week after the enrollment visit), with this amount increasing by $5 with each successive weekly self-report of cigarette abstinence along with a CO reading of ≤6 ppm (i.e., up to $40 in Greenphire clincard payments at 4 weeks post-switch; $150 total; see Table 1). After the switch day, participants with CO readings > 6 ppm will not earn the payment for that week, and the payment will reset to the starting incentive of $20.

e-Cigarettes (EC). Participants assigned to EC will receive the e-cigarette device and the same instructions described previously. Participants in the EC group will not earn incentives for cigarette abstinence, rather they will be yoked to a participant assigned to the (FI + EC) group and will receive the payment earned by that FI + EC participant (up to $150 total). Yoking will reduce or eliminate differential attendance rates between groups because participants can earn the same amount of money regardless of group assignment.

Safety Protocol for COVID-19. Data collection may take place inside the Homeless Alliance or outside in the homeless alliance courtyard. Participants may be asked to wear a mask while completing the survey and other study requirements. If participants do not have a mask then one may be provided to them. Hand sanitizer will be available to participants and staff. Depending on community transmission rates of COVID-19 and the comfort level of the staff, CO breath sample collection may take place outside in the courtyard. In addition, the number of participants who can be surveyed at once may be limited and social distancing guidelines may be implemented. All equipment will be wiped down following each use. Staff may wear masks while interacting with participants and handling equipment.

Sub-Study Visits.

Recruitment/Screening (Visit 1, Screening & Scheduling). Eligible participants who complete the screening survey will be given a chance to review the consent form. Study staff will provide the participant with ample time to review the study information and ask questions related to their participation. Participants who enroll will be scheduled to return for a baseline visit (typically within the next 7 days). The Homeless Shelter Alliance case workers, who work

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with the shelter's guests, may encourage their clients to enroll and retain participation in the study.

Baseline (Visit 2). Enrolled participants will be randomly assigned to the EC or FI + EC condition. Enrolled participants will be asked to provide their personal information (name and phone numbers). Participants will be instructed to switch from combustible cigarettes to e-cigarettes at bedtime or 10:00 pm (whichever occurs first), on the evening prior to their next scheduled weekly session. They will be provided with a EC device and they will have the opportunity to try it out. They will be provided with 7 pods (5% nicotine).. They will keep the pods in order to practice using the e-cigarette device over the week prior to their switch date. Participants will be advised about earning financial incentives for switching to ECs or yoking) beginning the following week on the quit/switch day. The schedule of payments will be discussed with all participants (see Table 1). Participants will be instructed not to use THC-containing vaping products and "street" vaping products, and not to modify or add chemicals to their vaping supplies while they are enrolled in the study. They will be counseled to use only the supplies that they are given by study staff, and to avoid dual use of e-cigarettes and cigarettes or other combustible products, including marijuana. Participants will receive a $10 Greenphire clincard paymentfor completing this visit and they will be provided with a Tracfone (or similar "burner" phone) along with a prepaid phone plan that will cover the study period to facilitate communication between the participant and study staff. Participants will be encouraged to complete this visit as soon as possible, but it can be completed within 21 days of visit 1. Enrollment into the sub-study will cease once 60 participants are enrolled.

Switch Day (Visit 3; 1 week after baseline). Participants will complete self-report questionnaires on a laptop computer; and expired CO and weight will be measured in a private area of the shelter to ensure confidentiality. Participants assigned to the FI + EC treatment will receive an additional $20 paymentif their expired CO level is $\leq$ 8 ppm (please note that the less stringent cut-off of 8 ppm will be used to verify abstinence on the first post-switch day only, because of the recency of switching). EC participants will receive the same payment as their yoked FI + EC counterpart. Attempts will be made to contact participants who do not attend study visits, in order to obtain self-reported smoking status. Participants will be supplied with pods in the flavor(s) of their choice, based off of what research staff has available, and based on their pre-switch smoking level.

1-4 Weeks Post-Switch (Visits 4-7). Participants will complete self-report questionnaires on a laptop computer; and expired CO and weight will be measured in a private room to ensure confidentiality. Participants randomized to the + EC group will receive an additional $20-$40 credit for self-reported abstinence and CO readings $\leq$ 6 ppm. EC participants will receive the same payment as their yoked FI + EC counterpart. Additional pods will be provided at each weekly visit based on pre-switch smoking levels. Participants will be

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provided with 1 additional e-cigarette device *only if* they lose or damage the first device. Participants will not be provided with any e-cigarette supplies after visit 7, to determine whether they continue to use the e-cigarette on their own.

8 Weeks Post-Switch (Visit 8). Participants will complete self-report questionnaires on a laptop computer; and expired CO and weight will be measured in a private area to ensure confidentiality. Participants will receive a $50 for completing this final follow-up visit, and participants may keep their study phones. Participants will be advised that they can receive free smoking cessation treatment through the Tobacco Treatment Research Program[36] or the Oklahoma Tobacco Helpline[65] and provided with contact information.

Table 1. Sub-study compensation schedule.

	Assessments	Incentive/ Yoking	**Total Possible Earnings**
Visit 1 (Brief Screening)	$0	$0	$0
Visit 2 (baseline/enrollment; 1 week pre-switch)	$20	$0	$20
Visit 3 (switch Day)	$20	$20	$40
Visit 4 (1-week post-switch)	$20	up to $25	$45
Visit 5 (2 weeks post-switch)	$20	up to $30	$50
Visit 6 (3 weeks post-switch)	$20	up to $35	$55
Visit 7 (4 weeks post-switch)	$20	up to $40	$60
Visit 8 (8 weeks post-switch)	$50	$0	$50
Total Possible Earnings	**$170**	**$150**	**$320**

E. Statistical Methods

Survey Study. Day shelter guests (up to 1000) using shelter services will have the opportunity to participate in the survey study. Study staff will enroll unique participants each month (i.e., participants may participate only once). Descriptive statistics will be generated (e.g., frequencies, means) to describe the characteristics, needs, tobacco use history, and tobacco treatment preferences of study participants, along with correlation and regression analyses to identify cross-sectional relationships among variables. For example, we will examine the percent of individuals who have used e-cigarettes as a means of quitting smoking as well as the percent who are interested in switching to e-cigarettes in the future. Tobacco use history and preferences for tobacco cessation treatment will be described (e.g., means, frequencies). The relations between tobacco use and health, other health behaviors, sociodemographic (e.g., education, race/ethnicity, gender), and personal characteristics (e.g., stress and mental health) will be examined via correlation and regression analyses. The rate of missing data and missing data patterns will be examined before analysis. If the combined missing rate is very small, say less than 5%, then we may safely perform the data analysis on the available data. If the missing rate is high, then we will explore sequential multiple imputation (SMI) as described by Raghunathan et al.[66] The analysis results from SMI data will be compared with those from the available data.

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Sub-Study. A sub-sample of survey participants (*N* = 60) who are currently smoking cigarettes will be randomized to one of two intervention groups and followed for ten weeks (2-weeks pre-switch through 8-weeks post-switch). This pilot study will provide feasibility data and intervention effect sizes for the power analysis for a future fully-powered randomized controlled trial. Descriptive statistics will be employed (e.g., frequencies, means) to characterize combustible cigarette cessation, cigarette reduction, daily EC use, and dual EC and combustible cigarette use. The intervention groups will be compared on CO-verified cigarette abstinence at 4 and 8 weeks after a scheduled switch attempt using logistic regression analysis. Secondary analyses will focus on reductions in cigarette smoking, EC use/switching, and dual use of ECs and combustible cigarettes.

F. Gender/Minority/Pediatric Inclusion for Research

The study has no inclusion/exclusion criteria based on gender or race/ethnicity. Children < 18 years of age will be excluded from participation in the survey study. Children and young adults <21 years of age will be excluded from the sub-study because tobacco products are only legally available to adults 21 years and older.

G. Human Participants

1. **Participant Population.** The overall survey study will include up to 1000 individuals recruited from the Homeless Alliance day shelter. Interested individuals may be included in the study if they: 1) are able to speak and understand English 2) are ≥ 18 years of age. The Day Shelter primarily offers services to adults, and rarely children. Children and families are referred to other locations that are safer for children (e.g., where individuals are screened for felonies and sex offenses). The sub-study will include 60 individuals who meet the sub-study inclusion criteria: 1) ≥ 21 years of age (verified by state driver's license or ID card), 2) have an expired CO level ≥ 8 ppm suggestive of current smoking, 3) report currently smoking ≥ 5 cigarettes per day, 4) willing and able to attend 8 study visits over an 10 week period (2 weeks pre-switch through 8 weeks post-switch), 5) interested in switching from smoking cigarettes to e-cigarettes, 6) willing to abstain from smoking marijuana/cannabis and other combustible tobacco products for the duration of the study, 7) able to speak and understand English, 8) demonstrates > 6th grade English literacy by earning a score ≥ 4 on the Rapid Estimate of Adult Literacy in Medicine-Short Form (REALM-SF; i.e., required to complete tablet/laptop questionnaire items), 9) is able to read a 3-sentence selection from the consent form, and 10) is not pregnant or breast feeding or planning to become pregnant. Individuals may be excluded from participation based on professional judgement in situations that would interfere with study participation such as apparent alcohol or other substance intoxication, uncontrolled psychosis, cognitive impairment, verbal or physical aggression directed towards study staff or other guests, or other extreme situations. New participants who approach the study team and participants who completed

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the primary survey in the past (pre-COVID – Before March 2020; before the start of the sub-study) may participate in the sub-study if they currently meet eligibility criteria. Going forward, potential participants will only be screened once for the sub-study and the CitiCare ID Number will be referenced to verify that the participant has not been screened more than once. Due to the targeted population, bus passes may be provided at visits to assist participants in coming back to their next appointment.

2. **Sources of Research Material.** Demographic, psychosocial, environmental and behavioral data will be collected via traditional self-report questionnaires completed in-person on password protected and encrypted OUHSC laptop or tablet computers. Expired CO will be collected to confirm self-reported smoking status. Height and weight will be collected. Attendance will be noted by the research staff each week for sub-study participants. Sub-study participants may be contacted by phone to assess tobacco use status if they do not attend in-person follow-up sessions.

3. **Recruitment and Informed Consent.** Participants will be recruited by study staff when they access services as the Homeless Alliance Day Shelter. The Homeless Shelter Alliance case workers, who work with the shelter's guests, may encourage their clients to enroll and retain participation in the study. Individuals will be provided with detailed information about the study, allowed as much time as needed to review the consent form, and given the opportunity to have their questions answered by knowledgeable research staff. Individuals may participate at a later date if they would like to give their participation further consideration. Written informed consent will be obtained from those who are interested in participating in the sub-study. The parent survey study requires a waiver of informed consent because the parent survey is anonymous. Instead, participants will review a cover letter that briefly describes the survey study and invites them to participate.

4. **Risks.** Participation in this study poses minimal risk to participants. However, one potential, although unlikely, risk to participants is loss of confidentiality. The severity of harm in the case of loss of confidentially may range from mild to severe depending upon the individual and the specific circumstances. However, the risks of participation in the study are comparable to participation in standard tobacco cessation treatment, as loss of confidentially may be experienced in either case.

   Risks of e-cigarettes and dual use of cigarettes and e-cigarettes (Sub-Study only).
   Possible risks of using *e-cigarettes*. The risk of side effects and adverse events are very low. These products are sold online, and at e-cigarette specialty stores and convenience stores nationwide, without a prescription. Nevertheless, all participants will be screened for pregnancy, and monitored for adverse events during the study period. Study personnel will assess for

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adverse events via self-report at all follow-up visits. Smokers will also be provided with a study phone number to report adverse events between follow-up visits. Serious adverse events will be reported to the Principal Investigator (Kendzor) and then to the OUHSC IRB. Participants who have a serious adverse event, become pregnant, or begin to breastfeed may be withdrawn from the study. The most likely adverse event, nicotine overdose, is anticipated to be rare. Mild symptoms (e.g., nausea, headache, disrupted sleep) will be handled quickly (e.g., advice to reduce or stop EC use). Lab studies of toxin exposure suggest that ECs incur no greater risk to health than do conventional cigarettes. ECs generally show lower levels of harmful and potentially harmful constituents. EC studies have reported mild and tolerable side effects that generally resolved completely over time with continued use (90% of cases); the most predominant of which were mouth/throat irritation, cough, and headache. In randomized clinical trials, no serious adverse events were reported and the e-cigarette group and the nicotine patch groups had comparable numbers of adverse events.

E-Cigarette and Vaping-Related Lung Injury (EVALI). Recent information indicates that EVALI is primarily (though not solely) associated with THC-containing vaping products acquired from informal sources,[24] which contained the product additive - vitamin E acetate.[25-27] A total of 2,711 hospitalized EVALI cases (including deaths) have been reported to the Centers for Disease Control and Prevention, with 60 confirmed deaths. However, since September 2019, EVALI hospital admissions have sharply declined to only a few cases in January 2020,[28] possibly due to increased public awareness of of the risks associated with THC-containing e-cigarette use, removal of vitamin E acetate from vaping products, and law enforcement actions taken to reduce the availability of illicit products.[30] Symptoms of EVALI include: coughing, shortness of breath, chest pain, nausea, vomiting, stomach pain, diarrhea, fever, chills, and weight loss.[67] Due to the determination of the causes of EVALI and the sharp decline in cases, the CDC is no longer tracking EVALI.

Risk of *dual use of cigarettes and e-cigarettes*: The concern about smokers engaging in dual use is that they will substantially increase their uptake of nicotine, leading to nicotine overdose. The symptoms of nicotine overdose include nausea, vomiting, dizziness, headache, and rapid heart rate. In a previous trial with ECs, none of the participants reported any indication of nicotine overdose in their dual use of e-cigarettes and conventional cigarettes. In fact, most reduced their level of conventional cigarette use in proportion with their uptake of e-cigarettes. Preliminary analyses (n=20) from another randomized trial that is investigating the use of ECs by caregivers as a means of reducing their children's secondhand smoke exposure (i.e., parents asked to use EC anytime they are in the home, car, or around their child), indicate that caregivers decreased in their level of salivary cotinine (a metabolite of nicotine; Mbaseline=447.9 to M3-mo=314.8). Caregivers' also

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reported reduction in number of tobacco cigarettes per day from baseline to 3- month follow-up (Mbaseline=19.6 to M3-mo=9.5). Consistent with these findings, parents reported no adverse events, no serious adverse events and specifically no nicotine overdose event.

5. **Protections against Risk.** Because survey participants can only participate once in the parent survey, we will track participant names and shelter ID numbers. These identifiers will be kept in password-protected data file that is separate from all other questionnaire data. Thus, specific survey participants cannot be linked with their questionnaire responses. This tracking file will be destroyed after all participants complete the study. In the questionnaire data files, each participant will be assigned an identification number that will be utilized in place of names. Informed consent documents will be collected electronically or stored in locked filing cabinets at the TSET Health Promotion Research Center. Electronic data will be maintained on the investigators' computers, and all computers will be encrypted and password protected. All project staff will receive training focused on each of the following topics: 1) project rationale and objectives, 2) the informed consent process, 3) general data collection procedures (e.g., computer data collection, privacy), and 4) use of the Vitalograph CO ecolyzer. Participants will be educated about the potential health risks of e-cigarette use (i.e., long-term heath impact is unknown); and dual use of e-cigarettes and combustible cigarettes (i.e., possible adverse health impact). Study staff will monitor sub-study participants for nicotine-related side effects/adverse events at each visit and participants will be provided with a phone number to call if they have concerns between visits. For sub-study participants who miss a study visit, staff will attempt to follow-up with them every week via phone to monitor the use of nicotine products during the study period.
   Potential Benefits. The knowledge gained from this study may be used to improve our understanding of the characteristics and needs of homeless adults and inform shelter decision-making regarding the availability of services. For sub-study participants, it is possible that these interventions will reduce harm by reducing combustible cigarette use and increasing the likelihood of switching to exclusive e-cigarette use.

6. **Risks in relation to Benefits.** The current study involves minimal risk. The *sub-study risks are* like *that of participation in any intensive smoking cessation intervention (e.g., loss of confidentiality, nicotine withdrawal*, nicotine product side effects). Participants receiving any of the interventions in the sub-study may benefit from cigarette reduction/cessation, and participants will be compensated for their time and effort. Conversely, continued combustible cigarette smoking is known to cause cancer, cardiovascular and lung disease.

H. Data and Safety Monitoring Plan

The study poses minimal risk to participants, therefore continuous monitoring and

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reporting of events will be undertaken by the principal investigator (Dr. Kendzor) and other OUHSC faculty co-investigators (Drs. Alexander and Businelle). Unanticipated problems/adverse events will be promptly reported to the IRB by the research coordinator or study staff. Possible (though unlikely) adverse events might include side effects from e-cigarettes as well as compromised data security. Sub-study participants will be scheduled for weekly visits and medication side effects will be assessed. Procedures to minimize the risk of loss of confidentiality are described in section G under the heading *Protections against Risk*.

I. Literature Cited

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