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Responses to E-cigarette Message Source and Presentation

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INVESTIGATOR STUDY PLAN - REQUIRED

1. TITLE
Identifying and examining the effects of source and presentation on responses to electronic cigarette public education messages in young adult vapers and non-vapers – Part 2

2. EXTERNAL IRB REVIEW HISTORY*
NA

3. PRIOR APPROVALS:
The devices are not being tested for safety or effectiveness.

Conflict of Interest (COI):
NA

Clinical Engineering Department:
The sensor devices used in this study have not been evaluated by biomedical engineering.

Biohazardous Agents:
NA

Radiation*:*
NA

Students as Subjects*:*
NA

Data Science Core & Recruitment Core:
NA

UMCCTS Protocol Review Committee (PRC)
NA

4. OBJECTIVES*
The goal of the study is to conduct a crowdsourced testing to examine the effects of source and presentation of e-cigarette educational messages among young adults who currently vape and do not vape. The objectives are to examine young adults' self-reported responses toward message source (expert vs. peer), message sidedness (one-sided vs. two-sided), and messages combining both (source x message sidedness) about anti-e-cigarette messages.

Aim 1: To determine the optimal message source and presentation type for young adult vapers and non-vapers to increase acceptance of e-cigarette education messages and e-cigarette harm perceptions.

H1. Vapers will report more optimal psychophysiological responses than peer and two-sided messages.

H2. Non-vapers will report more optimal psychophysiological responses than expert and one-sided messages.

Please note that all procedures will be done with the appropriate personal protective equipment, which includes a mask and face shield for the researcher. Participants will be required to wear their mask for the entirety of the study.

5. BACKGROUND*

Young adults (18-24-year-olds) in the U.S. have the highest rates of e-cigarette use (vaping),[1] with 16-19% of this population identifying as current users, 44-48% ever users, and 11-16% susceptible never users.[2] Vaping can lead to nicotine addiction and initiation of cigarette smoking[3–7] and is associated with cognitive and affective disorders among young adults.[8] The U.S. Food and Drug Administration (FDA) has prioritized educating about the health harm of vaping among young adults. However, young adults may avoid[9,10] or reject[11] the current education messages, especially if they currently vape[12–14] or perceive the messages as "controlling."[15] It is urgently needed to increase acceptance of e-cigarette education messages[16] to influence their e-cigarette harm perceptions and vaping behaviors.[17–20]

Using a trusted source[21–24] and presenting messages appropriately[25,26] can increase message acceptance. According to persuasion theories, one's tobacco use status may influence individuals' response to a source and presentation of messages because vapers and non-vapers differ in their attitudes and personal relevance regarding tobacco use.[25,27–29] Unfortunately, no research has yet examined the impact of a message source[22,30] and presentation[25,31,32] on young adults' responses to e-cigarette education messages based on their vaping status. Evidence from research with cigarette smokers suggests that vapers will respond defensively to e-cigarette education messages, but non-vapers will not.[12,33] Vapers may trust a tobacco health information source with similar attributes (e.g., peer young adults)[29,34] and accept messages with balanced perspectives that both present negative health effects of vaping and acknowledge their potential reasons for vaping (two-sided; e.g., "vaping can be appealing if others are using it, but it can harm your health").[25,31,35] On the other hand, non-vapers may trust a source with credentials (e.g., scientists) [36–38] and accept information-only messages (one-sided; e.g., "vaping can harm your health").[13,35] Thus, it is critical to understand and use a trusted source and present messages that are appropriate for vapers and non-vapers to optimize vaping cessation and prevention efforts, making it an important area of study to improve current messaging.

The proposed research is guided by biobehavioral theories of tobacco regulatory science,[39,40] psychology,[15,41] and communication.[42,43] By using previously tested education messages,[44] we will determine an optimal combination of message source and presentation type to increase message acceptance and e-cigarette harm perceptions. We will compare the effects of two sources (expert and peer) and two message presentation types (one-sided and two-sided) for young adult vapers and non-vapers. We will use in-lab study for objective assessment of psychophysiological measures (heart rate, skin conductance, and eye-tracking) during message exposure (N=112) to determine optimal messaging. The goal of this study is to determine optimal message source and presentation for young adult vapers and non-vapers to increase message acceptance and harm perceptions using psychophysiology.

6. INCLUSION AND EXCLUSION CRITERIA*

We will recruit young adults (N=112; 18-24 years) from the greater Worcester area, who identify as 1-a) vapers (n=56) or 1-b) susceptible non-vapers (n=56) and fluent in English. All participants will have confirmed 12+ hour abstinence from ingesting tobacco/cannabis prior to beginning the study in the lab

Those who are not fluent in English will not be included in the study. Prisoners will not be included in the study. Pregnant women may be in the study if they choose, but we will not seek pregnant people to be in the study.

7. STUDY-WIDE NUMBER OF SUBJECTS*
NA

8. STUDY-WIDE RECRUITMENT METHODS*
NA

9. STUDY TIMELINES*
An individual's participation in the study will be a 45 minute at a one-time visit. We expect to complete the study within six months of enrolling the first participant.

10. STUDY ENDPOINTS*
The primary outcome measures include psychophysiological responses (cognition, arousal, attention) and self-reported measures of e-cigarette harm message and source perceptions (message acceptance, harm perceptions, reactance, message liking, source trust, attitudes, behavioral intentions).

11. PROCEDURES INVOLVED*

After providing informed consent, participants will be randomized to one of four experimental conditions in a 2 (Source: expert and peer) x 2 (Presentation: one-sided and two-sided) design. Data will be collected through iMotions, a psychophysiological data collection platform. We will track participants' eye movements using an eye-tracking device. We will assess heart rate and skin conductance with a sensor by attaching Velcro-strapped electrodes on the fingers of participant's nondominant hand. When the study begins, participants will complete pretest measures, view messages, during which they will be measured on their psychophysiological responses, and complete posttest measures. Messages (see Appendix-A) will be presented in a random order for at least 10 seconds. Between each message segment, a black screen and "get ready" screen will be presented for 10 seconds to return participants' heartrate and skin conductance levels to baseline. This meets the established amount of time (6 seconds) to collect heart rate and skin conductance.[45] This procedure will be repeated 18 times for the 18 messages. Finally, participants will complete measures on demographics, attitudes, and behavioral intentions. The entire procedure will take approximately 45 minutes. After completion, participants will be thanked and compensated $50 for participation. Participants will be extensively debriefed about the hypothetical nature of the message source, the health harms of using any tobacco product, and information about the Massachusetts Tobacco Quitline with contact information. We will provide a consent form and verbally reiterate this information.

In order to minimize subject harm as a result of being shocked by static electricity from the sensors, room temperature will remain above 65 degrees when running participants as the colder,

drier air is more likely to cause static shock. We will also follow all safety guidelines for the equipment. These include having participants wash their hands thoroughly, then use hand sanitizer, and then use an alcohol towelette to clean the finger the sensor will be placed. In addition, participants will be instructed to try to keep their hand still during the study to ensure the sensor does not move.

12. DATA AND SPECIMEN BANKING*
NA

13. Data Analysis and Management*
Data will be collected through iMotions, a psychophysiological data collection platform. All data will be saved on a password protected computer on the UMass Chan Medical School server. Upon completion of data collection, all data will be de-identified and stored on the UMass Chan Medical School OneDrive.

Visual inspection of heart rate will be performed prior to statistical analysis to determine if a monophasic pattern resembling a U-shaped pattern is present. Each participant will receive a change in beats per minute (BPM) score based on the second before viewing (baseline) minus each second of the 10-second viewing of the message. Then, the BPM change score will be averaged per theme and compared for the greatest deceleration of heart rate, signifying greater attention to the messages in that theme category. Skin conductance will be analyzed similarly but compared for greatest acceleration, signifying greatest attention. Lastly, dwell time on the message using milliseconds will be calculated for the area of interest within the message. Longest dwell time will signify most visual attention for each message theme category. We will take the mean score for the self-report measures and rank the messages accordingly.

14. PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS*
The device is not intended to induce any shock to participants. There is an extremely low chance that participants may experience electrical shock as a result of having sensors directly applied to participants' skin. This is similar to experiencing static shock from rubbing against the carpet. However, if they do, the severity is also extremely low. In order to minimize subject harm as a result of being shocked by the sensors, room temperature will remain above 65 degrees when running participants as the colder, drier air is more likely to cause static shock. We will also follow all safety guidelines for the equipment. These include having participants wash their hands thoroughly, then use hand sanitizer, and then use an alcohol towelette to clean the finger the sensor will be placed. In addition, participants will be instructed to try to keep their hand still during the study to ensure the sensor does not move.

15. WITHDRAWAL OF SUBJECTS WITHOUT THEIR CONSENT*
NA

16. RISKS TO SUBJECTS*
Risks to subjects involve experiencing a minor static shock as explained in #14 as well as being uncomfortable answering questions about tobacco use. Participants will be advised that they are free to refuse to answer any question that makes them feel uncomfortable. All observed or volunteered adverse events will be recorded through the IRB. Lastly, participants will be at

some risk of breach of confidentiality, which is the case with most research studies. There are no known or suspected risks to pregnant women who may coincidentally be enrolled.

17. POTENTIAL DIRECT BENEFITS TO SUBJECTS*

NA

18. VULNERABLE POPULATIONS*

- **Students or employees:** Students or employees of the University of Massachusetts Medical School will be eligible to enroll. Contacts with the study participants will be for assessment purposes only. No one on the research team supervises or has the ability to influence a subject's grades, academic success, or professional advancement. The PI on this project does not teach courses at this time. Since many students may fall in the study population criteria, we are requesting to advertise the study on student list servs (The Student Life Bulletin, The Graduate School of Nursing list serv, and School of Medicine list serv). When participants come for a visit, they will not be asked if they are a UMass Chan student.
- **Adults unable to consent:** Our recruiting and consent process (requiring us to see the adult in person and have them sign the consent form) will allow us to identify adults who do not have the capacity to consent. They are ineligible to participate.
- **Subjects who are not yet adults (infants, children, teenagers)**: Individuals under the age of 18 are ineligible to participate.
- **Pregnant women:** Pregnant women may be included in this research study. These requirements will be followed: No inducements, monetary or otherwise, will be offered to terminate a pregnancy. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. Individuals engaged in the research will have no part in determining the viability of a neonate.
- **Neonates of uncertain viability or non-viable neonates:** NA
- **Prisoners:** We will not enroll or conduct research procedures with individuals that are known to be prisoners. If enrolled subjects become incarcerated during the study, we will submit this information within five business days as Reportable New Information.

19. MULTI-SITE RESEARCH*

NA

20. COMMUNITY-BASED PARTICIPATORY RESEARCH*

NA

21. SHARING OF RESEARCH RESULTS WITH SUBJECTS*

It may be several years before the results of the research are available. If participants are interested in the results of the study, the research team will request participants' contact information to reach them when results are available. We can share participants' individual results with them if they ask. However, because these are research tests, they are for their interest only. The results cannot tell participants about their health or diagnose any condition. If they request the information, the results can be provided at the conclusion of the study via email.

22. SETTING

The study will take place at the Prevention Institute at the Shaw Building (5 minute walk from Sherman Building where office is located). The lab is a facility for conducting focus groups, interviews, and message communication material testing. The lab provides Internet access on Mac and PC computers to collect the survey responses. The lab also contains iMotions software and hardware which enables the collection of psychophysiological data using sensors. The data entry and analysis will take place at the Shaw and Albert Sherman buildings. In the event that data analysis takes place remotely (e.g., the research team's home), the members will use UMass Chan computer with UMass Chan secured network.

23. RESOURCES AVAILABLE

The PI is responsible and accountable for the implementation of the study in accordance with the proposed plan. The PI holds a doctoral degree and has extensive research experience including the conduct of a variety of studies relevant to the current study.

The Study Coordinator is a postdoctoral research fellow who holds a doctoral degree and has experience in research studies. The coordinator will coordinate and execute day-to-day activities at the study site and implementation-related tasks (recruitment and retention, running participants, survey assessments, laboratories, and data management, participant compensation). The postdoctoral fellow is responsible for obtaining the informed consent from participants. The postdoctoral fellow will devote 50% of their time to ensure the launch and completion of this study, as well as data cleaning, analysis, and dissemination.

The PI and/or postdoctoral fellow will meet with any staff member involved with this research via Zoom and in person to ensure that they are fully informed about the protocol and the research procedures. Furthermore, the PI and/or postdoctoral fellow will meet with the staff members at least once a week to review their specific duties and functions (e.g., setting up study, data analysis).

24. LOCAL RECRUITMENT METHODS

We will recruit 112 young adults between the ages of 18 and 24. Participants will be recruited from the greater Worcester area using email (See Appendix-C), flyers, and social media, advertising an opportunity to participate in a health messaging study. We will also send out the flyer to the following student list servs at UMass Chan: The Student Life Bulletin, The Graduate School of Nursing list serv, and School of Medicine list serv. Participants from other studies will also be contacted. Passive online screener will be used to determine eligibility. Potential participants will be directed to an online screener that will collect their contact information. Those who meet the eligibility criteria will be contacted to schedule the first visit.

$60 will be given to each participant at the conclusion of their visit in the form of a gift card. We will follow the policy of participant payment instruction The gift cards will be given out per the req of partici payment through email and text message. We will collect participants' email addresses and any other info required by partipant addresses to send them their gift card at the end of their visit. The gift cards will be sent from a umassmed.edu account within an hour after their visit. Then, the record of the participant's email address and address will be destroyed by the PI.

While this study is requesting to advertise to UMass Chan students, we do not aim for them to be the only participants in the study.

Additionally, participants will be recontacted if they meet the eligibility criteria to ask if they would be willing to be contacted to participate in future studies. Depending on their preferred contact method (e.g., email or phone), participants will be contacted via that method and asked if they would be willing to be contacted for future studies. There will be three attempts to contact participants. We will keep a list of those who say "no" (which include those who do not answer after the three attempts) and those who say "yes."

25. LOCAL NUMBER OF SUBJECTS

112 individuals will participate in the study.

26. CONFIDENTIALITY

Screener data will be stored on REDCap. REDCap is a secure web-based application for building and managing online surveys and databases. This application was developed at Vanderbilt University. If participants consent, we will retain the identifying information (name, phone number, email) from the screener data for 3 years after completion of the study to recontact subjects for future studies. However, the responses will be de-identified at the conclusion of the participant enrollment period. Thus, participants' contact information will not be linked to the participant response. If participants do not consent to storing their contact information, we will destroy their contact information from the database at the conclusion of the enrollemnet period.

UMass Chan deploys REDCap application for use by our researchers and their study collaborators. Clinical study groups utilize REDCap functions via an intuitive interface to generate custom databases and/or surveys for data collection and study management including site and personnel management. REDCap provides audit trails for tracking data manipulation and export procedures, as well as seamless data downloads to common statistical packages and data import from non-REDCap data sources. UMass Chan REDCap is supported by the Data Sciences & Technology Division of Information Technology (IT).

The UMass Chan REDCap application resides in a secure network environment based on ISO 27002 designed to support PHI data capture and storage.

All study data are collected using the iMotions 6.4 Biometric Research Platform, a secure, computer-based data collection platform. No self-report or psychophysiological data collected are directly linked to participant identifying information: self-report and psychophysiological data collected through iMotions are tracked using a unique, numeric study identifier that does not contain any personally identifying information. A monitor on the computer will track the participant's eye movements and three sensors on the participant's fingers will track heart rate and skin conductance. Each message will appear for ten seconds, which falls above the established amount of time needed (6 seconds) to collect heart rate and skin conductance levels for still messages. This will allow us to take into account baseline levels and time for heart rate and skin conductance to react. After each message, participants will answer the same measures included in the participant survey pertaining to responses toward the message and source, and

perceived message effectiveness. This process will be repeated 18 times for each of the two message sidedness conditions, resulting in a total of 36 different messages seen by participants. Afterwards, participants will be asked to complete additional measures related to actual message effectiveness (e-cigarette attitudes, risk beliefs, intentions to vape).

Between each message sidedness condition, individuals will see a blank black screen for 10 seconds, then a black screen with the words "get ready" for five seconds followed by another black screen for 10 seconds to return heart rate and skin conductance back to baseline. All methods are consistent with accepted standards of psychophysiological measurement for media studies.

Dr. Stevens and the research team will be responsible for file maintenance. Screeners will be electronically maintained throughout the course of the study for scheduling participants. Signed consent forms will be stored in a locked cabinet through the course of the study and only retrieved for IRB requests. Participant surveys and psychophysiological data will be stored on a password protected storage on a secured network. Files will be reviewed once per week to ensure all documentation is securely stored. The researcher will first make sure the consent form is in the locked cabinet and then ensure that each participant file from iMotions is electronically stored for each participant ID number. Study documents will be maintained for a period of 3 years after completion of the study.

27. PROVISIONS TO PROTECT THE PRIVACY INTERESTS OF SUBJECTS

All study activities will be conducted in a private setting. The collection of sensitive information about subjects is limited to the information necessary to conduct the research study. Subjects will be told that they can skip any question they wish.

28. COMPENSATION FOR RESEARCH-RELATED INJURY

This research presents minimal risk. No funds have been set aside for compensation.

29. ECONOMIC BURDEN TO SUBJECTS

None.

30. CONSENT PROCESS

Informed consent will be obtained. All members of the research team will be trained in Human Subjects and the handling of data to ensure confidentiality in order to obtain Institutional Review Board (IRB) approval from UMass Chan. Participants will be appropriately consented. This will include a clear understanding of the study objectives and procedures, content of the survey protocols that will be administered, and ample opportunity to have their questions answered, and prior to the surveys. Participation will be on a voluntary basis, and we will obtain written consent from participants after the detailed explanation of the study and opportunity to ask questions. The consent process for participation in the study will occur in-person. All research personnel will be research personnel will be familiar with HRP-090: Informed Consent Process for Research.

31. PROCESS TO DOCUMENT CONSENT IN WRITING

Consent for study participation will be done in writing. All research personnel will be familiar with HRP-091: Written Documentation of Consent. The consent form will require a signature from the participant. The participants' signatures will be obtained at the one time in-person visit.

32. DRUGS OR DEVICES

"There is no intent to collect safety and effectiveness data about the devices used in this study. FDA regulations do not apply and an IDE is not required."

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Appendix A. Copies of the messages

** Before seeing each message, participants will view one of the four directions below according to their assigned source condition.*

Condition	Expert		Peer	
	Expert 1 Government health org	**Expert 2 Medical school researcher**	**Peer 1 Young adults**	**Peer 2 Influencers**
Directions	Imagine that the following message was written by scientists.	Imagine that the following message was written by your doctor.	Imagine that the following message was written by young adults like you.	Imagine that the following message was written by a social media influencer that you follow.

Messages with Sidedness Manipulation

One-sided	Two-sided
Sleek design hides a deadly truth. Vapes contain ingredients that can cause cancer.	Vapes come in sleek design that makes them look cool. But these designs hide a deadly truth. Vapes contain ingredients that can cause cancer.
That's not "just vapor." Vapes have ingredients that cause lung disease and cancer.	Vape companies say that you're vaping "just vapor." But that's not true. Vapes have ingredients that cause lung diseases and cancer.
You wouldn't drink formaldehyde. Why would you vape it? Most vapes have formaldehyde.	Some people say that vaping isn't bad for you. But most vapes have formaldehyde. You wouldn't drink formaldehyde. Why would you vape it?
Trouble breathing? Vape flavors may cause lung damage.	Vapes come in cool flavors that make you keep wanting to use. But these flavors may cause you lung damage and trouble breathing.
Chemicals in these vape flavors can hurt your lungs.	Cinnamon roll, very vanilla. Mmm…sounds tempting, but chemicals in these vape flavors can hurt your lungs.
Chemicals in these vape flavors can cause cell and lung damage.	Sugar and spice and everything nice? NOPE. Chemicals in vapes can cause cell and lung damage.
Depression? What a vibe check. People who keep vaping are more likely to have signs of depression.	People vape for cool vibes. But people who keep vaping are more likely to have signs of depression. What a vibe check.

Vaping causes coughing and lung damage. Not a good look.	Influencers may make vaping look cool, but the coughing caused by lung damage? Not a good look.
The lung damage caused by vaping will never be cool.	Vaping is going viral, but you know what will never be cool? The lung damage caused by vapes.
Extra salty lately? That might be nicotine withdrawal. Vape addiction is REAL.	Some people vape to get in a good mood. But are you extra salty lately? That might be nicotine withdrawal. Vape addiction is REAL.
Chained to your vape? Nicotine addiction means losing your independence.	Adult smokers are vaping to stop being addicted to cigarettes. But you can get addicted to vaping. It means being chained to your vape and losing your independence.
Vaping companies create catchy terms for nicotine addiction. Hard pass.	"JUUL Buzz"? That's a catchy term. But that just means nicotine addiction. Hard pass.
Don't get hooked by the flavors. Some pods have as much nicotine as a whole pack of cigarettes.	It's easy to get hooked by the flavors. But it's a sham. Some pods have as much nicotine as a whole pack of cigarettes.
Some pods contain as much nicotine as 20 cigarettes. Don't get hooked by the flavors.	Think you're just vaping flavor? Some pods contain as much nicotine as 20 cigarettes. Don't get hooked.
Nicotine addiction won't give you much of a choice. Most vape products contain nicotine. Don't get hooked.	The flavors may be limitless, but nicotine addiction won't give you much of a choice. Most vape products contain nicotine. Don't get hooked.
Do your friends get salty if they haven't had a hit? That's nicotine addiction. JUUL pods contain nicotine - as much as a pack of cigarettes.	It may be fun to get that perfect hit with your friends. But do your friends get salty if they haven't had a hit? That's nicotine addiction. JUUL pods contain nicotine - as much as a pack of cigarettes.
Vaping with friends leads to fighting with friends. Nicotine addiction makes people moody and hard to be around, which really kills the vibe.	Vaping can give you and your friends a good vibe at first. But it can soon lead to fighting. Nicotine addiction makes people moody and hard to be around, which really kills the vibe.
You'll be hooked forever. Don't trade nicotine addiction to be on trend.	It may be today's big thing, but you'll be hooked forever. Don't trade nicotine addiction to be on trend.

Appendix B.

Health effects of nicotine

Thank you for participating in our study.

E-cigarettes are not safe. If you vape e-cigarettes, you could be inhaling seriously addictive levels of nicotine. Nicotine in tobacco can damage your brain, increase the chance of having a heart attack, and decrease your immune system. Any tobacco products – including e-cigarettes, cigarettes, e-cigarettes, smokeless tobacco like dip, cigars, cigarillos, hookah, roll-your-own – are always dangerous. The only safe tobacco is NO tobacco. For more information about the harms of tobacco and nicotine, please visit:
https://therealcost.betobaccofree.hhs.gov/vapes

https://www.thetruth.com/breathofstressair?cid=vap_search_googlepaidsearch_truth_brand_BOSA&gad=1&gclid=CjwKCAjwtuOlBhBREiwA7agf1mx8urYu2Ws_aoxOKuvW7id_4yUBQItPrScQfVuvxlnwzL-cQrkQ4xoCefIQAvD_BwE

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Quit vaping or support someone in their quit attempt

My Life, My Quit

My Life, My Quit™ is a specially designed program to help young people quit vaping or other tobacco products. **My Life, My Quit™** provides five free and confidential coaching sessions by phone, live texting, or chat with a specially-trained youth coach. You can text "Start My Quit" to 36072 or call toll-free 1-855-891-9989 for real-time coaching. You can also visit mylifemyquit.com to sign up online, chat with a live coach, get information about vaping and tobacco, and activities to help them quit. The program can send out materials and a certificate at the end of the program.

This is Quitting

This is Quitting powered by **truth®** is a texting program for young people who want to quit vaping. It is a free, confidential 60-day program during which participants receive texts with information, tips, and support. They receive daily text messages to help them prepare to quit and supportive texts from young people who have been through the program and know what it's like to quit. They can also text COPE, SLIP, STRESS, or MORE at any time for instant support, or MASSINFO for information specific to Massachusetts. Young people can sign up even if you

they aren't ready to quit – the texts they receive will give them strategies and practice quits to help build confidence and help them feel ready to quit.

To enroll in the program, youth text "VapeFreeMass" to 88709. Youth can also connect with their school nurse, counselor, or coach to help get them started.

Parents and other adults can also text QUIT to 202-899-7550 to sign up to receive text messages designed specifically for parents of vapers.

Source: National Jewish Health (2023). MyLifeMyQuit. https://www.mylifemyquit.com/

Appendix-C.

Dear [NAME],

My name is [NAME] and I am a research staff at the UMass Chan psychophysiological lab. We're still looking for participants to participate in a lab study to examine the psychophysiological responses (eye-movement, heart rate, skin conductance) of e-cigarette education messages. If you are interested, please fill out the screener. A member of our research team will be in touch with you if you are eligible for our study. Thank you for your interest!

Thank you!
Research Staff Name

INVESTIGATOR STUDY PLAN - REQUIRED

eIRB Section 7.0 Attachments Upload Checklist

Follow How to Manage Files in eIRB and upload the following items as applicable to your submission. This checklist is provided for your convenience and is not a requirement for review.

	Investigator Study Plan
	Sponsor protocol
	Research portion of the grant
	Human subjects portion of the grant
	Written approvals from ancillary reviews (Clinical Engineering, COI, IBC, PRC, RSC, Students as Subjects, etc.)
	Recruitment materials such as flyers, brochures, posters, scripts of radio ads, etc.
	Data collection sheets, case report forms, etc.
	Surveys, measures, instruments, etc.
	Measures to assess capacity to consent
	DMC or DSMB charter
	Data safety monitoring plan
	Adverse event log
	Investigator brochure or package insert for drugs
	Instructions for use or approved FDA labeling for devices
	Sponsor justification or FDA documentation for non-significant risk device study
	IND or IDE documentation
	Patient information sheet for Humanitarian Use Device
	Approval order for Humanitarian Use Device
	Product labeling for Humanitarian Use Device
	HIPAA waiver
	HIPAA authorization
	Authorization to contact form
	Consent form(s)
	Assent forms(s)
	Fact sheet(s)
	Multi-site communication plan
	Study staff training plan
	SOPs or Manuals of Operations
	Screening log
	Compensation log
	Certificates of translation or translator attestations
	Data use agreements, memoranda of understanding,
	Documentation of data/specimen anonymity (i.e., provider will never break the code)