Official title:

RESEC: RESpiratory Effects of E-Cigarettes in Obese Youth

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The Ohio State University Consent to Participate in Research

Study Title:	**RESEC: RESpiratory Effects of E-Cigarettes in Obese Youth**
Principal Investigator:	**Dharini Bhammar, PhD, MBBS**
Sponsor:	**Division of Medical Oncology- OSU**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

You are being asked to participate in this research study to learn more about how vaping behaviors can affect lung function, symptoms during exercise and activity levels in e-cigarette users with and without obesity. If you choose to participate, you would attend **five** study visits at OSU (three in the beginning of the study and two after one year). Each visit of testing can last 1.5-4 hours. During **the first visit**, you will 1) fill several surveys about your vaping and physical activity habits, surveys about quality of life and personal information and background, 2) provide a urine sample, 3) perform forceful breathing tests to measure your lung function, and 4) exercise on stationary bike. **On the second visit**, you will perform a 30-minute vaping session using your own e-cigarette device where we will measure how you

vape using a specific device called puff-topography. After your second visit, **you will be provided with an e-cig device and one pod pre-filled with e-liquid for practicing it at home before you are coming for a third visit.** You will practice for about 20 puffs per day with this device until your feel comfortable using the device. **On the third visit**, you will perform a 30-minute vaping session using the device that we provided to you. Breathing tests will be done before and after your vaping sessions. The **fourth and fifth visits will be identical to the first and second visits** and they will be completed 1 year later so we can measure how your health has changed after 1 year of either similar use or change in use of e-cigarettes. There is no direct benefit to you by participating; however, you will get a report and explanation of your lung function measurements. The risks of this study include discomfort in answering questions asked of you, risks of nicotine and e-cigarette exposure that are not fully known at this time, risks of breathing tests such as shortness of breath or dizziness, and risks of exercising such as sore muscles or changes in blood pressure or heart beat. More information about these risks can be found below. We will reach out to you every three months between the third and fourth visits with a short survey. It is very important that you complete these survey requests for our study. You will be compensated for your time and effort in this study.

1. Why is this study being done?

You are being asked to participate in this research study to learn more about how vaping behaviors can affect lung function, symptoms during exercise and activity levels in e-cigarette users with and without obesity.

2. How many people will take part in this study?

We expect that 42 people will complete all study visits.

3. What will happen if I take part in this study?

There are 5 study visits. The first two and last two visits are similar and will be separated by 1 year. The third visit will only be completed once. At each visit, you will complete some surveys and physical measures such as weight. At each visit, we will collect urine. If you are female, we will perform a pregnancy test to ensure you are not pregnant at the beginning of each visit.

Pre-visit instructions: You will be required to:

1. not exercise for 24 hours before study visits
2. not to have any caffeine (soda pop, coffee, tea) for 6 hours before each visit
3. not eat a heavy meal or drink anything (except for water) for 2 hours before study visits (snacks/light meals are ok)
4. be nicotine-free (abstinent from vaping) at least 12 hours before each study visit
5. be smoke-free (abstinent from smoking tobacco or any other products) for at least 48 hours before each study visit
6. For Visits 1 and 4, be dressed in exercise clothing and shoes

If you cannot or did not follow these instructions before any particular visit, please let us know and we will reschedule for another day! It is really important for research studies that all participants are tested under the same conditions, otherwise our results will not be valid. We check whether you have vaped or smoked using a monitor that you breathe into- if the level that it shows is high, you will not be able to participate in this study.

The following provides a summary of what will take place at each visit.

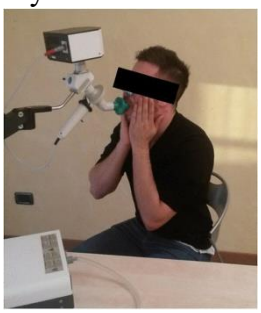
Visits 1 and 4 (3 to 4 hours each): On the first and fourth visits, you will do the following:

- Blow out into a device to check for levels of carbon monoxide in your breath to confirm abstinence from vaping and smoking
- Height, weight, and circumference measurements.
- Provide a urine sample
- Fill out surveys including medical history and tobacco use among others.
- Breathing tests: are also called a lung function tests and they consists of breathing hard into a machine several times. You will wear a nose clip during these tests. Each test takes a few minutes to complete and you will do each test a few times. We will explain each test before you do it and coach you during the test. You will be sitting in a body box which is a cylindrical chamber with a sliding door (see picture on the right). The tests will measure how big your lung are, how fast you can push air out of your lungs, and how easily oxygen can go from your lungs into your blood stream.

- Exercise test. The exercise test will be completed on a stationary bike (see picture on the right). You will be wearing a mask or a mouthpiece and nose clip so we can measure your breathing while you exercise. There will be a sticker on your forehead to measure your heart rate and oxygen levels. The exercise will last approximately 14-16 min. There are some breathing measurements that you will do during exercise such as taking a big breath in when we ask you to. We will check how difficult the exercise is for you and if you have any difficulty breathing. We will

repeat some breathing measurements after you finish exercise for 15-20 min. We will also ask you to fill our surveys about how your breathing felt during the exercise test.

Visits 2, 3, and 5 (1.5 to 2 hours each): You will blow into a device to measure how much carbon monoxide is in your breath to confirm abstinence from vaping and smoking, provide a urine sample, have your weight measured, and fill out surveys. In the second and fourth study visits, you will use your own e-cig and complete a vaping session in a specific room in our lab. Each vaping session will include a standardized, 5-minute, 10-puff vaping bout (30 seconds between each puff) followed by 30 minutes of ad libitum (as desired) vaping. During the vaping sessions, measures of vaping behavior (topography) will be assessed. You will not be allowed to eat or drink (other than water) during the vaping sessions. Before and after each vaping session you will do breathing tests and fill out a survey that assesses e-cigarette cravings. After visit 2, you will take home a study e-cig device and 1 pod with pre-filled tobacco flavored e-liquid to practice (20 puffs per day with the study device and until you feel comfortable using the device) using the device before visit 3. On the third visit, you will use the study e-cig and complete a vaping session similar to the one on the second visit. The fifth visit will happen after 1 year has passed and will include a vaping session that is done with your own e-cigarette device. You will complete one new breathing test during the fifth visit before and after the vaping session. This test is called "impulse oscillometry". It involves breathing through a mouthpiece for 30-40 seconds with your hands on your cheeks while we measure airway resistance in your small and large airways. There will be a tapping sound during the test which are just sound waves created by the device that allow us to get the measurements we need (see picture on the right). The 5th study visit will not be completed if you have quit vaping over 1 year.



4. How long will I be in the study?

You will be in this study for 1 year as we complete all five study visits on separate days. There will be 3 study days at the beginning and 2 study days after 1 year has passed. Depending on how your visits are scheduled, your ability to remain abstinent prior to each visit, and any technical problems we may need to repeat visits. Your total duration of participation will be 13 – 15 months.

Over this period, there will be 5 visits- the first and fourth visits will last 3 – 4 h and the second, third and fifth visits will last 1.5 – 2h, for a total of up to 14 hours.

There may be anticipated circumstances under which your participation may be terminated by the investigator without regard to your consent. Examples of when this may happen are, if you are not following the study requirements, become pregnant during the study, or for any other reason we feel your participation is not in your best interest or the study's best interest.

You can stop participating in this study at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher first.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Survey Risks

Some people feel uncomfortable answering questions about smoking or their health. You may choose to take a break from answering the surveys or choose to withdraw from the study if you wish to not complete the surveys.

Reproductive Risks for Women

If you are a female, you must not be and should not become pregnant nor breastfeed an infant while on this study. Using cigarettes or e-cigarettes while pregnant or breastfeeding may involve risks to an embryo, fetus or infant, including birth defects which are currently unforeseeable. In order to reduce your risk of pregnancy, you or your partner should use one or more acceptable methods of birth control regularly and consistently while you are on this study.

If you become pregnant or suspect that you are pregnant during this study, you should immediately inform the study personnel. We will conduct a pregnancy test at each visit to ensure that you are not currently pregnant. The study product may be discontinued until the result of the pregnancy test is known. If pregnancy is confirmed, you may be withdrawn from the study. Payment for all aspects of obstetrical, child, or related care will be your responsibility.

Lung Function Tests and Carbon Monoxide test

The lung function tests are routinely done in hospitals and labs all over the country and are not associated with any serious risks. Sometimes, repetitive efforts of breathing out forcefully within a short time frame may cause dizziness, light-headedness, shortness of breath or coughing. One of the tests where we measure how easily oxygen can go from your lungs into the blood stream includes breathing in a small mixture of gases including carbon monoxide and methane. There is no risk of breathing a small amount of these gases. There is no risk for performing the carbon monoxide test. If the level of carbon monoxide is higher than what we are looking for at the start of any study visit, you could be excluded from the study. There is no risk of performing the impulse oscillometry test.

Exercise tests

There is a slight risk of discomfort similar to those associated with any type of exercise. Examples of these discomforts may include, but not limited to, shortness of breath, leg fatigue and soreness, and discomfort from sitting on a bike seat. These discomforts have been reported in 2-20% of subjects tested. There is a slight risk of abnormal blood pressure, fainting, disorder of heartbeat, and in rare instances, heart attack with exercise. These risks occur in 1 in every 40,000 tests when the exercise is done till maximal effort. However, the level of exercise in this study is not at maximal effort, the risk of any serious problem is much lower. Also, you can always stop cycling if you feel uncomfortable or don't wish to continue.

E-cigarette Devices

All of the products in our study are currently available for purchase in stores; however, there was no FDA evaluation of these devices prior to their being commercially available. **As a result, we do not know the long-term safety, risks, or if these devices contain ingredients that are known to be toxic to humans.**

Loss of Confidentiality

Some of study information will be recorded the University approved Research Electronic Data Capture (REDCap) system and other information will be in paper files or recorded on password protected computers. Any information collected will be in a secure databases and locations that are accessible only to authorized study staff.

7. What benefits can I expect from being in the study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that the information learned from this study will help us to understand how body weight affects people's vaping behaviors and health.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

If we find information that significantly impacts your health, we **will** share it with you. The types of research results that will be shared include the lung function test results and the exercise test results. These will be shared as paper copies or secure attachments in an email. You will be notified either in person or over the phone about any results that significantly impact your health.

The NIH has issued a Certificate of Confidentiality for this study. This Certificate provides extra protection for you and your study information, documents, or samples (urine). The Certificates are issued so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place for you and your information, documents, or samples. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency that is funding this study requests the information, or if the FDA tells us to release this information. We may also use your information to conduct other scientific research as allowed by federal regulations.

10. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, it/they may be used or shared with other researchers without your additional informed consent.

11. What are the costs of taking part in this study?

Although there is no cost for participating in this study, there are costs such as transportation and potential loss of income that you may incur if you choose to participate. Parking is free at our location.

12. Will I be paid for taking part in this study?

By law, payments to participants are considered taxable income.

You will receive the following compensation for your time:

- Visits 1 and 4: **$75** each visit
    - Pro-rated as noted: $10 for consent and carbon monoxide test/ height and weight measures, $10 for completing all surveys, $25 for completing lung function test, and $30 for completing exercise test.
    - **If all the surveys are not completed on Visits 1 and 4, then compensation on visit 1 and 4 will be reduced by $10 and $10 will be added to the visits when you complete all surveys.**
- Visits 2, 3, and 5: **$50** each visit
    - Pro-rated as noted: $10 for the lung function tests and surveys, $30 for the vaping session, and $10 for the lung function tests and surveys done after the vaping session.
    - If you have quit vaping during the 1-year study gap, we will not conduct the 5th study visit for your health and safety.

The maximum amount you can potentially earn by end of study if you follow study instructions is $75 + $50 + $50 + $75 + $50 = $300.

Payments will be made using the Greenphire ClinCard, which is like a debit card, to increase accountability and facilitate ease of payment. You will receive your debit card at the end of the first visit. You will receive a handout that explains how to use this card. This card will be reloaded at the end of each subsequent visit. It is important that you do not lose this card because we cannot replace funds that are lost.

13. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

14. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Bhammar at 614-366-9467 or Dharini.bhammar@osumc.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Bhammar at 614-366-9467 or Dharini.bhammar@osumc.edu.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time