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PARTICIPANT ADOLESCENT ASSENT FORM

Title of Study: 'Cardiopulmonary complications of electronic cigarettes'

Principal Investigator:	**Dr. Michael Stickland**	**Ph: 780 492-3995**
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What is a research study?
A research study is a way to find out new information about something. Children do not need to be in a research study if they don't want to.

Why are you being asked to be part of this research study?
You are being invited to take part in a research study looking into how using e-cigarettes and/or vape pens affects the lungs of Canadian teenagers and adults.

You are being asked to participate because you meet the criteria for one of the study groups. You may be enrolled as:

- A control participant (you do not use e-cigarettes, smoke cigarettes, or smoke cannabis); or
- An e-cigarette/vape pen user; or
- A cannabis smoker; or
- An e-cigarette/vape pen user and a cannabis smoker.

If you become an adult during the study, you will be asked to sign a new adult consent form to continue taking part in the study.

If you join the study what will happen to you?
We want to tell you about some things that will happen to you if you are in this study. The study will look at your lung health while you are resting and while exercising.

If you agree to be in this study, you will be asked to sign this assent form before any part of the study is done.

The study will take place at the University of Alberta. There will be 4 study visits during this time. Each visit ranges from 2 to 4 hours. The complete study will take about 10 hours in total. You can take breaks as needed during the visits.

Visit 1: Screening, lung and exercise tests (3-4 hours)
This visit involves the following procedures:

1. **Blood Collection:** Providing samples of blood for analysis. Approximately 3 teaspoons of blood will be collected.

2. **Questionnaires:** Completing questionnaires about your health, e-cigarettes and/or vape pens use, cigarette use, and breathing symptoms.

3. **Cardio-Pulmonary Exercise Test (CPET):** Performing an exercise test to evaluate heart and lung function.

4. **Breathing Tests (Pulmonary Function Test (PFT)):**
    i. Spirometry: Blowing tests are part of routine care for lung diseases. For the test, you will be asked to take a deep breath in and then blow out really hard and fast for up to 6 seconds. This test tells the researchers how your lungs are working and how big they are. They will ask you to blow up to 8 times.

    ii. Diffusion Capacity: This is another breathing test. For this test, you will sit in a large clear box and breathe normally. After a few breaths, you will be asked to hold your breath for up to 10 seconds and then breathe out normally. It tells the researchers how well oxygen moves from your lungs into your blood. They may ask you to do this test up to 8 times and you will have a break between each test.

    iii. Oscillometry: This is another breathing test. For this test, you will sit on a chair with your back and neck straight and breathe through a machine for about a minute. You may be asked to repeat the test. This test tells the researcher how healthy your airways are.

5. **Activity Monitoring:** You will be given a smartwatch to wear on your wrist for 7 days to measure your physical activity. You should wear it at all times, except when charging if needed, during activities such as contact sports, or during activities involving water. You can remove the watch for brief periods if needed, but it should be put back on as soon as possible afterward. After the 7 days, you will return the smartwatch.

Visit 2: Exercise and Blood Vessel Function (~2 hours).
You will do several 6-second breath-holds while resting and during easy to very hard exercise. These breath-holds help us understand how the blood vessels in your lungs are working.

At the start of the visit, we will show you how to do the breath-holds and give you time to practice. During each stage of rest and exercise, you will do two breath-holds. We will measure your heart

rate, blood pressure, and oxygen levels throughout the test. We will also collect a small blood sample from your fingertip during each stage.

Visit 3: Blood Volume Movement and Blood Vessel Function (~2 hours).
You will do the same breath-holds as in Visit 2. This time, you will do them while your body is placed under different pressure conditions. These pressures help us study how blood moves in your body.

You will do two breath-holds at each stage. We will measure your heart rate, blood pressure, vein pressure, and oxygen levels throughout the test. We will also collect a small blood sample from your fingertip twice during the visit. You can take breaks or stop the procedure by letting a study member know.

1. *Resting breath-holds:* First, you will lie down and do two breath-holds under normal room pressure. Your lower body (from your hips to your toes) will be inside a chamber and sealed with a soft skirt to keep the air from leaking.
2. *Pressure breath-holds:* Next, you will stay lying down and do two breath-holds at each pressure level. The pressure in the chamber will be changed to move blood toward or away from your chest. These changes can feel like standing up or lying with your feet raised.

Visit 4: Ultrasound Imaging (~2 hours).
You will complete the same exercise as in visit 2 and the same pressure test as in visit 3. During all parts of the visit, a trained member of the research team will take pictures of your heart using an ultrasound probe and gel on your chest. The ultrasound uses sound waves to create images of your heart and is painless.

Will any part of the study hurt?
Questionnaires: You may feel uncomfortable answering some of the questions. You do not have to answer any question that you do not want to answer.

Pulmonary Function Tests: During the breathing test, you might breathe too fast, which could make you feel dizzy or faint, but this doesn't usually happen. The researchers will watch you carefully while you do the test to make sure you are okay. The mouthpiece you need to use might feel a bit uncomfortable because you have to breathe through it tightly. You might also get a dry mouth during the test, but you can drink water between tests if you want. There is a tiny chance of getting an infection from the machine, but we use a new filter for each person, and we clean the machine before and after every test.

CPET: This generally is safe but it may stress the heart, especially if you have heart problems. This could lead to irregular heartbeats, heart muscle issues, or even a heart attack. A research staff trained in first aid will watch you closely. They will stop the test if there are signs that it is unsafe for you to continue. You can stop the test at any time if you feel unable or unwilling to continue.

Sharing of Information: There may be non-physical risks associated with taking part in this study, such as the risk of revealing your private information. All efforts will be made to keep your data confidential. All information collected from you will have a secret study code.

Unexpected Results: The tests may discover a finding that the researchers were not looking for. The findings will be looked at by a research member, and you will be informed of these findings.

Will the study help you?
There may not be a direct benefit to you from taking part in this study.

Will the study help others?
The study might find out things that will help other children who use e-cigarettes and/or vape pens someday.
What do you get for being in the study?
You will get up to $300 if you complete all 4 study visits.

Do you have to be in the study?
You do not have to be in the study. It is up to you. No one will be upset if you do not want to do this study. If you join the study, you can change your mind and stop being part of it at any time. All you have to do is tell us. It is okay, the researchers and your parents will not be upset.

Who will see the information collected about you?
The information collected about you during this study will be kept safely locked up. Nobody will know it except the people doing the research.

The study information about you will not be given to your parents. The researchers will not tell your friends or anyone else.

What if you have any questions?
You can ask any questions that you may have about the study. If you have a question later that you did not think of now, either you can call or have your parents call 780-492-1121.

Other information about the study.

- If you decide to be in the study, please write your name below.

You will be given a copy of this paper to keep.

_ Yes, I will be in this research study. _ No, I don't want to do this.

Child's name	Signature	Date

Person obtaining Assent	Signature	Date