

**Characterizing the Repeatability and Reproducibility of Cardiovascular Responses to Hypoxic
Apneas**

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1-052 Li Ka Shing Center
Edmonton, AB, Canada
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PARTICIPANT CONSENT FORM

Title of Research Study: Characterizing the Repeatability and Reproducibility of Cardiovascular Responses to Hypoxic Apneas

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Why am I being asked to take part in this research study?

You are being asked to take part in this research study because you are healthy. Our aim is to study the consistency of your body's response to breath holding. All of today's procedures have been done on humans before and are considered safe.

This form contains information about the study. Before you read it, a member of the study team will explain the study to you in detail. You are free to ask questions if there is anything you do not understand. You will be given a copy of this form for your records.

What is the reason for doing the study?

The response to breath-holding is well-known. Previous studies have shown that breath-holding slows your heart rate and constricts your blood vessels. This response is known as the diving reflex and is known to be larger after you breathe low oxygen concentrations. The degree of consistency in how much your heart rate slows and how much your blood vessels constrict when you do several breath holds is unknown. We want to directly measure the differences in these responses between breath holds. You will do a series of breath holds on two testing days. We will compare your heart rate, blood pressure, oxygen saturation, and respiration between breath holds.

What will happen in the study?

If you meet the criteria for this study, you will be asked to come into the Neurovascular Health Lab (VVC 4-269). The location of the lab is at the University of Alberta room 4-269 in the Van Vliet Centre building on 87 Ave and 114 St NW. It is accessible by city transit and near two train stations (University or Health Sciences/Jubilee). You will need to visit the lab twice on back-to-back days.

Requirements: You will be asked not to eat anything for 2 hours before coming into the lab. We also ask you not to have any caffeine, cannabis, or alcohol 12 hours before coming into the lab. Finally, please do not go to the gym or do any physical activity other than normal walking / stair climbing within 12 hours before coming into the lab.

You will be most comfortable if you wear a tank top or short sleeve top that is loose fitting (males may go topless if they wish). We ask that persons with long hair tie it up. Once in the lab, it is important that you are comfortable and relaxed and tell us if anything is wrong or uncomfortable.

We will collect some basic information about your general health as well as your height and weight. At this point we can address any questions or concerns you might have. Then you will lie in a hospital bed, and we will begin to put on the equipment required to do the study.

Equipment:

- One set of electrocardiogram stickers will measure your heart rate during the experiment. The set has three stickers. One sticker goes on your left shoulder, one goes on your right shoulder, and one goes on your left side.
- An arm cuff will go around one arm to take blood pressure like your doctor would. A small finger cuff will also go on the middle finger of the same arm. This finger cuff lets us measure your blood pressure during every heartbeat.
- A strap around your chest will measure the effort of each breath.
- A mouthpiece will go between your lips and teeth before holding your breath. We will also use a nose clip to make sure you only breathe through your mouth. We will show you how to remove the mouthpiece during your breath-holds.
- A finger clamp will go on your pointer finger to measure the oxygen saturation of your blood in the same way as in a hospital.

Once the equipment is in place, we will start the test.

Protocol: The protocol will begin before instrumentation with a series of baseline measures. This includes the following:

- 1) You do a forced vital capacity test where we measure your lung volume.
- 2) You do a warm-up maximal breath-hold.

After the baseline measures, we will complete instrumentation. You will then get to sit still for two minutes and relax. This will give us normal resting values. Next, we will do the following:

- 1) Maximal breath-hold after breathing a gas mixture of low O₂ for 5 minutes.
- 2) Rest and recover for 5 minutes.
- 3) Second maximal breath-hold after breathing a gas mixture of low O₂ for 5 minutes.
- 4) Rest and recover for 5 minutes.
- 5) Breath hold for the same duration as the longest of your two maximal breath holds (i.e., points 1 and 3) after breathing a gas mixture of low O₂ for 5 minutes. We will ask about your rating of perceived exertion on a scale of 1-10 after each test apnea.
- 6) Rest and recover for 5 minutes.
- 7) Repeat points 5 and 6 four more times.

You will return to the lab after 24 hours and repeat the same in-lab test. The only difference on the second day is that you will use the maximal time from the first day as your target time for steps 5 to 7 rather than the maximal time from the second day.

What are the risks and discomforts?

Breath-Holding- Voluntary breath-holding is commonly used in human respiratory physiology. You may feel breathless and may become anxious. During extreme breath holding (more than 5 minutes) oxygen levels may drop to less than 75% and carbon dioxide may increase to more than 55 mmHg. However, the typical response is much less than this and changes are reversed immediately upon resuming breathing. We do have supplemental oxygen on hand should you need it.

Blood Pressure Monitors- The finger and/or arm cuff for measuring blood pressure may cause some discomfort including numbness, tingling, or discoloration (bruising) in the finger or arm. These will return to normal soon after the cuff is removed.

Decreased oxygen- You may feel as though you need to breathe harder and faster and may feel breathless. This is normal and expected. The researchers will be watching all variables continuously throughout the test. If your oxygen saturation drops below 75% we will stop the test or indicate that you may stop breath-holding. You can stop the test at any point if you feel uncomfortable. The feeling of breathlessness will go away as soon as you breathe room air. We have supplemental oxygen should you need it.

Mouthpiece and Nose clip- the mouthpiece and nose clip may cause some discomfort but will return to normal soon after they are removed.

Covid-19- In-person interactions with other people and travel may increase your risk of exposure to Covid-19. Research will be done in accordance with current University and AHS guidelines.

Other- If we find out anything new during this research which may change your willingness to be in the study, we will tell you about these findings.

What are the benefits to me?

You are not expected to benefit directly from being in this research study.

What will I be asked to do while I am in the study?

We ask you not have any caffeine the morning of your in-lab tests or cannabis / alcohol 12 hours before. Finally, please do not go to the gym or do any physical activity other than normal walking / stair climbing 12 hours before your visit.

You will be most comfortable if you wear a tank top or short sleeve top that is loose fitting (males may go topless if they wish). We ask that persons with long hair tie it up. Once in the lab, it is important that you are comfortable and relaxed and tell us if anything is wrong or uncomfortable.

You will also be asked to maintain your normal exercise and diet habits on the day between tests.

What happens if I am injured because of this research?

If you become ill or injured because of being in this study, you will receive necessary medical treatment, at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities. If you suffer a research-related injury, please call Dr. Craig Steinback at 780-492-5553. Should you need urgent medical care, please go to the hospital.

Do I have to take part in this study?

Being in this study is your choice. If you decide to be in this study, you can change your mind and stop being in the study at any time.

Can my participation in the study end early?

You are free to withdraw from this study at any time for any reason. You can do this by contacting the investigators. If after participating in the study you wish to remove your information from the study, you have until December 31, 2025, to do so. After this time all the information will be used. We may request that you withdraw from the study during the protocol if we are at all worried about your general health (i.e. high blood pressure, irregular heart rhythm etc.). We will notify you of our reason should this occur.

What will it cost me to participate?

It will not cost you to participate in this study.

Will I be paid to be in the research?

If you require, we have two parking spots reserved in a covered lot nearby. Alternatively, you can be reimbursed for parking up to \$15 per visit in cash.

Covid-19 Mitigation Strategies

The researchers follow the most up-to-date provincial, municipal and institution specific requirements related to Covid-19 safety.

Privacy and Confidentiality

During this study we will be collecting information (or “study data”) about you. We will use the data to help answer research questions and we will share (or “disclose”) your information with others such as other researchers.

Below we describe in more detail how your data will be collected, stored, used, and disclosed.

What data will we be collecting?

During this study we will be collecting data about you. Examples of the types of data we may collect include your name, where you live, your racial background, your age, your health conditions, your health history, your medications and results of tests or procedures that you may have had. We will only look for and collect the information that we need to do the research. We will get this information by asking you questions and doing the tests outlined in this form.

How will the study data be stored?

The study data we collect that has your name will be securely stored by the research coordinator during and after the study. At the University of Alberta, we keep data stored for a minimum of 5 years after the end of the study.

The study team will not release your name to anyone unless the law says that they must.

How will the study data be used?

Your study data will be coded (with a number) so that it no longer contains your name, address, or anything else that could identify you. Only your research coordinator will be able to link your coded study data to you. When the study is done the data will be anonymized.

Any data collected will be kept in a locked cabinet. Digital data will be stored in a password protected and encrypted computer. Only study investigators have access to these data. Your name will be excluded. We will only use the data collected for research purposes. Any research data published because of this study will be presented as group data and will not identify you as a participant. Study data (your name excluded) will be kept indefinitely.

Who will be able to look at my health data?

During research studies it is important that we get accurate data. Therefore, your study data may also be seen by people from the University of Alberta auditors and members of the Research Ethics Board.

By signing this consent form you agree that the research staff can collect, use and disclose information from your study data as described above.

If you want to see your study data, please ask the study team. You will be able to look at your study data and can ask for any mistakes to be corrected. The study team may not be able to show your study data right away and you may have to wait until the study is completed before you can see your study data.

What if I have questions?

If you have any questions about the research now or later, if you experience any adverse effects, or think that you have suffered a research-related injury please contact Dr. Craig Steinback at 780-492-5553.

If you have any questions regarding your rights as a research participant, you may contact the University of Alberta Research Ethics Office at reoffice@ualberta.ca. This office is independent of the study investigators.

This study is funded by the Natural Sciences and Engineering Research Council of Canada (NSERC).

How do I indicate my agreement to be in this study?

By signing below, you understand:

- That you have read the above information and have had anything that you do not understand explained to you to your satisfaction
- That you will be taking part in a research study
- That you may freely leave the research study at any time
- That you do not waive your legal rights by being in the study
- That the legal and professional obligations of the investigators and involved institutions are not changed by your taking part in this study.

SIGNATURE OF STUDY PARTICIPANT

Signature of Participant

Name of Participant

Date (DD/MM/YYYY)

SIGNATURE OF PERSON OBTAINING CONSENT

Signature of Person Obtaining Consent

Name of Person Obtaining Consent

Date (DD/MM/YYYY)

SIGNATURE OF THE WITNESS

Signature of Witness

Name of Witness

Date (DD/MM/YYYY)

A signed copy of this consent form has been given to you to keep for your records and reference.