**Consent and Authorization Form**

**Principal Investigator: Brian Strickland MD**
**COMIRB No: 23-0468**
**Version Date: 04/28/2023**

**Study Title: Effects of Continuous Positive Airway Pressure on Peripheral Oxygen Saturation, Work of Breathing, and Exercise Tolerance at Altitude**

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

### Why is this study being done?

This study plans to learn more about ways to improve oxygenation, work of breathing, and exercise tolerance at altitude. Respiratory distress is frequently experienced by travelers at high elevations, and is more pronounced in individuals engaged in physical exercise. In many cases, this can become severe enough to cause immobilization and difficulty carrying out evacuation procedures. Supplemental oxygen has been traditionally used for improving oxygen saturation difficulty breathing for climbers and travelers requiring rescue, but its use is limited by heavy tanks and limited compressed oxygen supply. Continuous positive airway pressure (CPAP) has also been shown to improve oxygen saturation among subjects at altitude, but until recently, use of CPAP has had similar obstacles to supplemental oxygen. However in recent years devices have become portable and are frequently used in the backcountry. This study aims to evaluate the degree to which CPAP can improve oxygen saturations and improve work of breathing among individuals exercising at altitude, as a way to determine its effectiveness as a rescue device.

You are being asked to be in this research study because you are a healthy adult. Your previous and current experience in this environment makes you uniquely suited to help us determine whether CPAP can be an effective tool to improve oxygen saturation and exercise tolerance in high altitude locations.

### Other people in this study

Up to 25 people from your area will participate in the study.

### What happens if I join this study?

If you join the study, you will travel to a high elevation location (Mount Evans, 14,200 feet) and undergo a 1000 foot hike. We will provide transportation to this location if you wish, you may also take your personal vehicle there. Your vital signs, including oxygen saturation and rate of breathing, will be taken while hiking and breathing either ambient air or using CPAP. After signing this form, you will be fitted with a CPAP mask. You then will begin walking back the Mount Evans trail while your SpO2, respiratory rate, and heart rate are continuously recorded. Study staff will also ensure that you are able to safely around any obstacles, such as rocks or

other hikers. Upon arrival to the end of the trail, the mask will be removed, and final vital signs will be taken. You will be allowed one hour to rest and rehydrate, then repeat the study by switching into the other group (CPAP to ambient air, or ambient air to CPAP), Upon repeating the study and again taking their finishing vital signs, your participation will be considered complete. All questions and concerns will be addressed at that time, and drinks and snacks will be provided. Your study participation time will last approximately 4 hours in total.

During the study, you will be carrying the CPAP device, as well as its battery, in a backpack that will be provided. The total weight of this is approximately 5 pounds (2.3 kg). The purpose of this is to study the effect of the device's inherent portability, and to eliminate the long tubing that would be required if someone else carried it. This will make your participation safer and free of loose equipment and hoses which can be caught on rocks and other obstacles encountered on the trail.

**What are the possible discomforts or risks?**

Discomforts you may experience while in this study include discomfort from the CPAP device, minor orthopedic injuries, and acute mountain sickness (AMS). The CPAP device, while very light and easily carryable by one person, requires the placement of a mask on your face. While this mask is frequently tolerated by individuals who use it while sleeping, it can cause some claustrophobia in some people. The mask will be properly fitted prior to use in order to avoid this sensation, and you will be able to easily remove it at any time. If the CPAP device were to fail or run out of batteries, the mask will still allow you to breathe normal ambient air. Additionally, participation in this study does require walking on a trail and some uneven terrain, which risks minor orthopedic trauma such as bruises and sprains. We will make sure that the trail remains free from obstacles and point out any hazards along the way in order to prevent these from happening. If you do fall or sustain any injuries, we will provide local treatment using one of the first aid kits provided by study staff, who are also trained in emergency medicine and first aid. If this is not possible, we will carry phones and satellite communication equipment to assist in your evacuation to a medical facility at lower altitude.

While at altitude, any traveler is at risk of developing acute mountain sickness (AMS). While not life-threatening, this illness consists of headache, nausea, and dizziness. It usually only occurs in travelers who have been at altitude greater than 6 hours, and is treated by descending to a lower elevation. While you will be exposed to sufficient altitude to cause AMS, we do not anticipate that you will be in this location long enough to experience any of these symptoms. If you do, we will provide transportation to a lower elevation immediately in order to resolve your AMS symptoms.

Other possible risks include exposure to the elements, such as wind, rain, and lightning. Prior to participating in this study, we will have thoroughly checked emerging weather patterns in the Mount Evans area. You will only be allowed to participate if these weather patterns are exceedingly unlikely to occur. If during the study, inclement weather does occur, you will be taken immediately to shelter until it is safe to leave.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed. All of your data will be entered into a secure encrypted database, and any papers used will be destroyed

### What are the possible benefits of the study?

This study will allow researchers to learn more about how to improve blood oxygen levels and exercise performance at high altitude. Exposure to high altitude can cause difficulty breathing and decreased exercise capacity, and if CPAP can improve these problems and risks of traveling at altitude, high elevation locations will be safer for travel and more enjoyable to experience. The CPAP device may also be found to be an effective rescue device, assisting patients who are experiencing altitude-related illnesses, without the weight of large oxygen tanks.

This study is not designed to treat any illness or to improve your health.

### Will I be paid for being in the study?

You will not be paid to be in the study.

### Will I have to pay for anything?

You will not be charged for any of the study procedures or equipment used in the study.

### Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

### Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

### What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Brian Strickland immediately. His phone number is 913-961-9491.

In the event of an illness or injury resulting from your participation in this study, you should seek appropriate medical care. However, you and/or your insurance company will have to pay for that care.

### Who do I call if I have questions?

The researcher carrying out this study is Brian Strickland MD. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Brian Strickland at 913-961-9491. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Brian Strickland with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Who will see my research information?**

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Brian Strickland MD
3111 W 34th Ave.
Denver CO 80211

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.

- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed.

**Information about you that will be seen, collected, used and disclosed in this study:**

- Demographic Information (age, sex)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, medical history
- Research Visit and Research Test records

**What happens to Data that is collected in this study?**

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study is important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belongs to you.
- The investigators of this research may study your data collected from you.
- If data is in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

**Agreement to be in this study and use my data**

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____

----------Use the following only if applicable----------

**A signature of a witness is required for consent of non-reading subjects and consent using a short form.**

Witness Signature: _____ Date:_____

Print Name:_____

Witness of Signature •

Witness of consent process •