

Official Title: Applied Physiology of Oxygen Toxicity: Mechanisms in Humans

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Consent To Participate In Research Study

"Applied Physiology of Oxygen Toxicity: Mechanisms in Humans"

IRB #Pro00112396

Concise Summary

The purposes of this study are to: (1) test a method to see if it could increase personal endurance and reduce excessive rise in blood carbon dioxide during underwater exercise in divers; and (2) understand the mechanisms by which this endurance can be impacted by commonly used medications, changes in habit, such as sleep deprivation or fatigue, or exposure to environmental changes, such as increased levels of carbon dioxide.

Stamina during a dive and the ability to control blood carbon dioxide depend on the function of the respiratory muscles (mainly diaphragm). It has been shown that training the breathing muscles can increase exercise endurance, including during a dive.

In this study, we will test the effect of daily respiratory muscle training on breathing muscle performance and underwater exercise during a dive to 98 feet of sea water. At the same time, we will measure blood carbon dioxide and lactic acid levels obtained from a small catheter placed in a wrist artery.

The study will require preliminary testing for eligibility. If eligible, study procedures include a dive, then one month of daily 30-minute breathing exercises. Following that, a second diving exercise test will occur. This second test will be performed in conjunction with either a commonly used medication (such as caffeine or other stimulant), a change in habit (such as sleep deprivation), or exposure to elevated levels of carbon dioxide. You will be randomly assigned to one of these interventions for the second test.

The main risks of this study include (1) bruising and also blockage of the blood supply from the arterial line that could lead to permanent injury or loss of your thumb or hand; (2) adverse effects of chamber compression on your ears or sinuses, leading to pain and hearing loss; (3) decompression sickness due to gas bubbles forming in tissues and blood, which can cause pain in the joints, skin rash, numbness, damage to the brain, spinal cord, or lung leading to disability, and even death. Benefits may include learning a method of increasing your exercise endurance.

If you are interested in joining this study, please continue reading below.

You are being asked to take part in this research study because you are a healthy male or female between the age of 18 and 45 years of age. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As the study doctor or study staff discuss this consent form with you, please ask him or her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study staff if you are taking part in another research study.

A grant from the US Navy will sponsor this study. Portions of Dr. Moon's and his research team's salaries will be paid by this grant.



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WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, Drs. Richard Moon and Bruce Derrick will conduct the study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine whether training of the respiratory muscles with added low-dose non-toxic levels of carbon monoxide will improve underwater endurance. A secondary aim is to assess how other variables (medication, sleep deprivation, and carbon dioxide) impact these changes and to better understand the mechanisms underlying these physiologic adaptations.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 60 people will participate in this study.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. You will have the following tests and procedures to make sure that you are eligible:

Pre-Study Procedures for Eligibility Screening

- A. You will initially participate in a subject briefing and have an opportunity to ask any questions regarding the study, particularly the expected discomforts and your right to stop participation at any time.
- B. Complete a medical history and physical exam. To participate in this study you must be 18-45 years of age, a non-smoker, not pregnant, not have either sickle cell disease or sickle cell trait, and pass a screening physical prior to the start of the test activities in the study.
- C. Undergo a 12-lead electrocardiogram — a painless test that measures the electrical action of your heart.
- D. Blow into a machine to determine the fitness of your lungs (spirometry and maximum breathing capacity). Spirometry measures how much air you breathe in and breathe out, and how quickly you breathe out. Maximum breathing capacity (MBC) measures how much air you can breathe in and out of the machine for 12 to 15 seconds. Your sensitivity to carbon dioxide will also be tested. This consists of breathing increasing levels of carbon dioxide and measuring the resulting increase in breathing (ventilatory sensitivity to carbon dioxide or so-called ‘hypercapnic ventilatory response’).
- E. If you are a woman who could get pregnant, you will provide a blood or urine sample for a pregnancy test before each dive.
- F. If you are of African American descent, you will have blood drawn for screening of the sickle cell trait. Some information suggests that individuals with sickle cell trait may be at higher risk of sudden death during exercise. Whether this is the case for diving is not known with certainty, however this test is being performed out of caution and concern for the safety of our research participants.
- G. You will perform a strenuous exercise test (VO₂max test) on a stationary bicycle over a 10-20 minute period at an increasing workload until you stop the exercise due to fatigue or discomfort. A doctor will monitor your heart rate and waveform (ECG) during this period. You will be unable to participate if your oxygen consumption at maximal effort is less than 35 mL/(kg*min) for males or less than 30 mL/(kg*min) for females.
- H. Painless measurement of the thickness of your diaphragm using ultrasound. A mark will be placed on the ultrasound probe placement site using a long-lasting but temporary marker.



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- I. Voluntary breathing endurance test. This consists of a measurement of how long you can breathe at maximum effort against a resistance, typically a few minutes.
- J. You will then undergo a variety of breathing tests to determine how well your lungs function. These tests include ventilatory sensitivity to carbon dioxide testing, voluntary breathing endurance test, diaphragm thickness measurement, maximum diaphragm pressure measurement, spirometry, maximum voluntary ventilation (MVV).

Investigational Research Study Activity

After the screening procedures above, you will perform the following on a separate day:

1. Baseline underwater exercise test. A catheter will be inserted into an artery in your wrist after injection of local anesthetic. You will then enter the hyperbaric chamber, which will be compressed to an equivalent depth of 98 feet and exercise underwater (29 – 30 °C) at a level near your previously measured peak work capacity for 10 minutes. Blood samples will be obtained periodically to measure levels of oxygen, carbon dioxide, lactic acid and pyruvic acid.
2. This may be followed by respiratory muscle training. This will consist of 4 weeks of daily, 5 days per week 30-minute sessions, during which you will breathe through a mouthpiece with a nose clip. Every 30 seconds a beep will signal you to take a full inhalation and exhalation, which will occur against a resistance. The resistance will be increased by a small amount each week. You will be randomly assigned (like the flip of a coin) to breathe either air or a low concentration of carbon monoxide during these training sessions. During the final week, at the end of one of these sessions, a teaspoonful of blood will be obtained to measure carbon monoxide level in the blood.
3. Experimental underwater endurance test. The baseline underwater exercise test will be repeated, but with the addition of one of the following conditions: sleep deprivation; sleep deprivation + stimulant medication (caffeine or methylphenidate); exposure to warm and cold water (19 – 20 °C). You may wear a device on your head that measures blood flow while underwater during some of these tests; or exposure to elevated levels of carbon dioxide.

For those selected to the sleep deprivation condition, you will wear for 24 hours an activity tracker, which is similar in size and appearance to a watch. During the daylight hours, you are free to do whatever activities you would normally do (except for sleeping). During the nighttime hours, you will report to a location with staff present to ensure you do not sleep overnight. Then, after being awake for 24 hours, you will be driven to our facility to undergo the various study activities. After these activities, you will be provided a ride home to ensure your safety.

For those randomized to elevated levels of carbon dioxide, you will take 6 teaspoons of sodium bicarbonate over the course of several days to achieve a blood level of carbon dioxide consistent with elevated carbon dioxide levels.



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There is an optional part of this study that involves drawing a small blood sample (approximately 2 teaspoons) to be processed and DNA extracted and stored in the Duke Biobank for genetic and epigenetic studies. Later in this form, you can indicate whether you opt-in or opt-out of this part of the study.

HOW LONG WILL I BE IN THIS STUDY?

The pre-study sessions described earlier will generally require 4-5 hours on one day. In order to maximize each subject's performance on the underwater exercise apparatus, familiarization will be required, and may require some additional time on an individual basis (between 1 and 5 hours). The main research activities will take place at least one day later. The first dive will occur on a third day, requiring around 3 hours total time. This will then be followed by daily respiratory muscle exercise training, each session lasting around 30 minutes. The final day of testing and the second dive will require 4-5 hours, unless you are assigned the sleep deprivation study, which will involve wearing an activity tracker and not sleeping for 24 hours prior to the study activities.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE STUDY?

As a result of your participation in this study, you are at risk for the following side effects. You should discuss these with the study doctor and your regular health care provider if you choose:

More likely:

1. Risks associated with drawing blood from your arm: These include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
2. Injection of local anesthetic prior to placement of the arterial catheter: Pain can occur, although this is usually short-lived.
3. Barotrauma: With compression there is occasional difficulty getting the air pressure in the ears, sinuses, teeth, lungs and intestines to equal the increasing pressure outside the body. Such problems may cause pain and the production of fluid in these spaces. Other possible effects include hearing loss, inflammation of the ear and sinusitis. Usually, these problems are temporary and clear in a few days. Very rarely permanent problems occur. If any discomfort is felt during compression, the personnel in the laboratory should be immediately notified so that corrective measures can be taken.

Less likely:

1. Risks of decompression sickness (DCS): You may develop signs or symptoms of DCS as a result of the dive. DCS symptoms are due to gas bubbles forming in tissues and blood. The most common symptoms are usually joint “awareness,” pain in the joints (mostly mild pain in the knees or ankles and occasionally elbows or shoulders), skin rash, and numbness. Other possible symptoms include coughing or chest pain on breathing (the chokes), blurred vision, vertigo (dizziness), hearing loss, tingling, numbness, weakness, inappropriate fatigue, and severe headache. This can involve damage to the brain, spinal cord, or lung leading to disability, and even death. The risk of serious decompression sickness in the test is very low. We will monitor you for the presence of bubbles in the veins and arteries using ultrasound. You will be removed from an experiment if arterial bubbles are found even if no symptoms of decompression sickness develop.



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Treatment of DCS: Recompression in a hyperbaric chamber is usually effective for treatment of DCS. Recompression therapy is available on site in the Duke Center for Hyperbaric Medicine and Environmental Physiology where the altitude studies will take place. Recompression therapy is very effective in treating decompression sickness especially if it is administered quickly after symptom onset. Nevertheless, there is a very small risk of a serious episode of decompression sickness that will not completely resolve with recompression treatment.

You will be monitored constantly during the research study activities, and there will be medical staff available at all times who are prepared to intervene if there are any problems.

2. Risks associated with equipment failure: If there is mechanical or electrical failure of part of the pressure tank or of the equipment which keeps it operating safely, the exposed humans could be seriously injured or even killed. If a fire occurs within the pressure tank, all exposed humans could get burned or asphyxiated (suffocated). However, the Duke hyperbaric chambers have a very good safety record: in over 50 years of operation, there have been no instances of serious structural failure, and no resulting injuries to personnel or experimental subjects. Nonetheless, the possibility of equipment failure, however remote, cannot be completely eliminated. Minor problems have happened including:
 - A structural problem that occurred during an altitude study. In this problem the O-ring seal on the chamber's "medical lock" door was damaged during an altitude study when a subject improperly closed the door. The chamber lost vacuum and the simulated altitude decreased from 11,500 to 8,000 causing some brief discomfort due to ear popping in the subjects before it was recognized and corrected. A procedural checklist to minimize the risk of similar future events was put into place. This could not occur during a dive, as planned for this study.
 - A fire occurred during compression of an unoccupied chamber due to the use of a ball valve containing a flammable substance (nylon) through which 100% oxygen was being delivered at high pressure. This occurred in 1980, since which time all new equipment is subjected to evaluation and testing before its use.
3. Risks associated with a maximal exercise test: The bicycle test you may be asked to perform is a graded VO_2 peak test (it measures your use of oxygen during exercise). What this means is that the workload will gradually be increased on the bike, and the test continues until you are exhausted, or the attending physician stops the test based on information he or she gathers about you during the test. The physician has well-defined rules to end the exercise, but the normal reason to stop the test in a healthy person is exhaustion. This may not be a pleasant end-point for the test, especially if you rarely exercise to exhaustion. Occasionally, people who exercise feel lightheaded, become short of breath, develop chest pain, or develop irregularities of their heart beat that are natural responses. During recovery from exercise, some may become faint. On very rare occasions death (0.005% or 1 in 20,000) or heart attack (0.02% or 1 in 5,000) has occurred during exercise. These risks are associated with exercise testing that has been documented primarily from a high-risk population (patients with heart disease or suspected heart disease). The likelihood of these problems occurring in asymptomatic (neither causing nor displaying symptoms), healthy subjects is low, but not impossible. The attending technician will explain the bicycle exercise to you in great detail. An Advanced Cardiac Life Support (ACLS)-certified physician and two test operators certified in cardiopulmonary resuscitation (CPR) will be present during the exercise testing and ECG monitoring will be used as a safety precaution.



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4. Risks associated with catheter placement: Infection and allergic reaction to the local anesthetic. Arterial catheter insertion in the wrist can cause bruising and also blockage of the blood supply that could lead to permanent injury or loss of your thumb or hand.

5. Risks of Seizure: There is a rare risk of developing a seizure in the hyperbaric chamber due to increased oxygen to the brain. Study staff are trained to detect these seizures in the chamber and tend to subjects. When seizures do occur, they typically are very brief. Subjects recover within minutes. After a seizure and recovery, hyperbaric oxygen can be continued immediately. These type of seizures do not develop into lasting seizure disorders.

6. Risks of Medications:

- **Caffeine**: This medication is the most commonly utilized stimulant in the world and is ingested by a great fraction of people each morning via coffee. Although exceedingly well tolerated, caffeine may induce a feeling a general feeling of unrest or even cause benign cardiac arrhythmias. We will administer 500 milligrams of caffeine to participants by mouth. The FDA regulates caffeine in medications and food and generally cites adverse effects with rapid doses exceeding 1,200 milligrams.

- **Methylphenidate**: This medication has been utilized for many years for the treatment of depression and inability to concentrate. As such, it is FDA approved to treat attention deficit hyperactivity disorder (ADHD). Methylphenidate is also used clinically in the setting of narcolepsy. It is exceedingly well tolerated, but can cause nervousness, irritability, and nausea. We will administer a single dose of 5 milligrams per mouth to each participant.

- **Clevidipine**: This medication is used clinically to tightly control blood pressure. Commonly, physicians utilize clevidipine in the intensive care unit and operating room as it is easy to titrate quickly and to achieve narrow blood pressure goals. We will use this same medication to control blood pressure as it achieves excellent blood pressure control and is a medication commonly utilized in clinical settings by the research investigators. It is well tolerated in various clinical settings, but may cause low blood pressure. The starting dose per the manufacturer guidelines is 2 milligrams per hour intravenously, which then can be adjusted upwards to achieve a desired blood pressure. Clevidipine has been FDA approved for these indications since 2008.

- **Sodium bicarbonate**: This medication is an antacid and commonly utilized to treat heartburn, upset stomach, and indigestion. It is extremely well tolerated and has very few side effects, which usually involve loss of appetite or nausea. We will utilize 6 teaspoons of sodium bicarbonate daily to achieve a serum bicarbonate level consistent with chronic carbon dioxide exposure. This dosing regimen has been utilized in prior studies and demonstrates an exceedingly low risk approach for any side effects.

Potential Risks and the Genetic Information Non-Discrimination Act (GINA): There is a potential risk of loss of confidentiality. Every effort will be made to protect your confidential information, but this cannot be guaranteed. The genetic information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, secure location at DUHS, accessible only by authorized members of the study team, and will not



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be disclosed to third parties except as described in this consent form, with your permission, or as may be required by law. Your entire set of genes will not be decoded as part of the genetic research.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Risks to an unborn child:

Female. Pregnancy can affect your body's exercise capacity. In addition, low levels of oxygen can have harmful effects for a developing pregnancy, especially later in pregnancy. Women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in this study.

If you are a woman who could possibly become pregnant, a blood or urine pregnancy test will be done before each dive session. Because pregnancy tests do not give positive results in the week after conception, it is possible to miss a very early pregnancy. If you are sexually active with a partner who is able to father children, you should either abstain completely from vaginal intercourse from the time of your screening visit until after the last study session, or use an effective method of birth control for the same length of time. Your study doctor will discuss appropriate methods of birth control with you.

If you think there's any chance you might be pregnant during the study, let your study physician know right away.

Unknown risks: There may be risks, discomforts, drug interactions or side effects that are not yet known.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law. Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in the Duke Hyperbaric Center, Room 0587A.



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Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration and/or the Duke University Health System Institutional Review Board. If your research records are reviewed by any of these groups, they may also need to review your entire medical record. As part of the study, results of your study-related laboratory tests, imaging, and procedures may be reported to the Navy. A representative from the Navy may be present at certain study visits/procedures. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives and affiliates of the US Navy, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record. Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

All of the blood and study procedures are being done only because you are in this study. The study results will be provided to you but will not be sent to your physician unless you request it.

The study results will be retained in your research record forever. Any research information in your medical record will also be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Photographs are taken to demonstrate protocols used in research studies. You will be asked if you agree to be photographed before any are taken. If taken, such photographs might be presented at meetings describing the research, in which case a bar will be placed in the photograph over the area of your eyes to make the photograph less identifiable. You will not be identified nor will your individual results discussed in such cases.

Please read the sentence below and put your subject initial next to your choice. No matter what you decide to do, your decision will not affect your care.

1. "I agree to be photographed."

Subject's Initials

2. "I do not agree to be photographed."

Subject's Initials

PHYSICIAN AVAILABILITY

A doctor experienced with altitude and hyperbaric medicine is available before, during, and after the test. This includes the initial medical screening and a pre-test physical to ensure that you are healthy before the test. During the test, the physician will be available to follow your progress. In the event of a problem, the doctor will stop the test and will direct any treatment you need, including recompression in the hyperbaric chamber, and medical follow-up after a treatment. You will have access to the doctor to specifically address any post-test concerns at any time during or following the study.



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ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You will not receive medical benefit from participating in this study; there is the possibility to observe the effect that respiratory muscle training may have on your endurance during steady exercise. This study may also provide a safe method to maximize underwater performance of Navy divers. However, none of this can be guaranteed.

ARE THERE ANY RESTRICTIONS ON MY ACTIVITIES BEFORE OR AFTER THE STUDY?

You will be required to be available in person or by phone for 24 hours after completion of the study to be checked for symptoms of DCS. If you do develop symptoms you must be available and willing to come to Duke Hospital for evaluation in person. You must not fly in an airplane for 24 hours after completion of the study.

WHAT ARE THE COSTS?

There are no costs associated with participation in this study. If you require treatment for decompression sickness you will not be charged for the medical care.

WHAT ABOUT COMPENSATION?

You will receive \$50 compensation only if you are accepted into the study but disqualified prior to the investigational activities because you do not meet study requirements. Total possible compensation for completion of the study is as follows:

Screen, including exercise tests	\$50		
Underwater endurance test #1	\$500		
Training Sessions (for RMT group)			
#1	\$10	#11	\$20
#2	\$11	#12	\$21
#3	\$12	#13	\$22
#4	\$13	#14	\$23
#5	\$14	#15	\$24
#6	\$15	#16	\$27
#7	\$16	#17	\$28
#8	\$17	#18	\$29
#9	\$18	#19	\$30
#10	\$19	#20	\$31
Underwater endurance test #2	\$500		
TOTAL POSSIBLE COMPENSATION for those in RMT group	\$1,501		
TOTAL POSSIBLE COMPENSATION for those not in RMT group	\$1,050		



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WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Moon at 919-684-8762 during regular business hours and at 919-970-5290 (pager) after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

It is necessary that you read and understand several general principles that apply to everyone who takes part in this study:

1. Taking part in this study is entirely voluntary. You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concern an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be provided to the Duke University Health System.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Richard Moon in writing and let him know that you are withdrawing from the study. His mailing address is: PO Box 3094, Duke University Medical Center, Durham, NC 27710. At that time we will ask your permission to continue using all information about you that has already been collected as part of the study prior to your withdrawal.

Nonparticipation or withdrawal from this study will not affect your job status if you are a Duke employee and will not affect your grades if you are a Duke student.

2. There will be no charge to you for taking part in this study.
3. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

STORAGE OF SAMPLES

As part of this study, with your permission we would like to store and use your identifiable blood for future research. If you agree to allow your blood to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. Please read the sentence below and put your initials next to your choice. No matter what you decide to do, your decision will not affect your care.

"I agree to allow my identifiable blood to be stored for future research"

Subject's Initials

"I do not agree to allow my identifiable blood to be stored for future research"

Subject's Initials



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If you opt-in and later decide that you do not want your blood to be stored for future research, we ask that you contact Dr. Moon in writing and let him know you are withdrawing your permission for your identifiable blood/urine/DNA to be used for future research. His mailing address is: **Dept. of Anesthesiology, Box 3094, Duke University Medical Center, Durham, NC 27710, USA**. At that we will ask you to indicate in writing if you want the unused identifiable blood/urine/DNA samples destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

However, your samples and data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. Of note, when your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them

The use of your samples may result in commercial profit. You will not be compensated for the use of your samples other than what is described in this consent form.

A description of this clinical trial will be available on <https://clinicaltrials.gov/> as required by US Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, please contact the principal investigator (study doctor), Dr. Richard Moon (pager 919-970-5290), or Dr. Bruce Derrick (pager 919-970-9792). You will be given current contact phone and pager numbers for the 'on call' physician during the medical watch period following chamber exposures. These will be recorded on a disposable hospital wristband for you to wear for 48 hours following exposure in the hyperbaric chamber.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

Signature of Subject

Date

Time

Signature of Person Obtaining Consent

Date

Time