DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
Effects of Ketosis on CNS Oxygen Toxicity - II

Phase 2 Adult Consent Form

CONCISE SUMMARY

The purpose of this research study is to understand how ketogenic food products affect oxygen toxicity in undersea divers. We hope this will provide a starting point to develop methods for improving the safety of Navy divers, warfighters and submariners.

Participants in the study will undergo a physical exam and blood testing as part of the screening process and take part in experiments on two separate days. On the first day of the study, there will be one experiment in the hyperbaric (high pressure) chamber, which will be adjusted to simulate 35 feet below the surface of the ocean. Before going into the chamber, the participant will drink either ketogenic food products or placebo (regular) food products. Participants will be immersed in water to the shoulders, inside a hyperbaric chamber while breathing 100% oxygen and doing cycling exercise. Testing on the cognitive software, as well as blood sampling and physical monitoring will be done while in the chamber. After the exercise test, the chamber will be returned to normal pressure. On the second day of the experiment, participants will drink the opposite food product (ketogenic or placebo) as the first experiment. The second experiment in the chamber will then be the same as the first.

The most common risks associated with study activities include drawing blood (momentary discomfort and/or bruising, infection, excess bleeding, clotting, or fainting) and pain associated with catheter placement. Risks associated with breathing high levels of O2 include vision disturbances, ear-ringing, nausea, twitching, tingling, irritability, dizziness, poor concentration, difficulty speaking, loss of consciousness or seizure. Risks associated with the ketogenic food products are mild nausea, vomiting, diarrhea, abdominal cramps, mild intermittent constipation (difficulty moving your bowels), and mild intermittent hunger.

If you are interested in learning more about this study, please continue to read 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 39 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 staff discusses 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.

If you are currently taking part in another research study, please tell the study staff at this time.

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Dr. Bruce Derrick will conduct the study. It is funded by Naval Sea Systems Command. The sponsor of this study, Naval Sea Systems Command, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Derrick's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate Dr. Bruce Derrick will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to understand how ketogenic food products affect oxygen toxicity in undersea divers. Oxygen toxicity affecting the central nervous system, mainly the brain, is a result of breathing higher than normal oxygen levels at elevated pressures as can be seen in SCUBA diving or inside a hyperbaric (pressure) chamber. This is a condition that may cause a wide variety of symptoms such as: vision disturbances, ear-ringing, nausea, twitching, irritability, dizziness, and potentially loss of consciousness or seizure. Because ketogenic food products have been used to reduce or eliminate seizures in humans, it may be beneficial to reduce oxygen toxicity as well. We hope this study will provide a help to develop practical and useful methods for improving the safety of undersea Navy divers, warfighters and submariners.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 70 people will take part in this study at Duke.

WHAT IS INVOLVED IN THE STUDY?
Before you continue reading there are several important considerations:

- Study participation is voluntary.
- Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled.
- You may discontinue the study at any point.
- 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.
- If you participated in an earlier phase of this study you must wait at least one week until completing the study procedures below.

Pre-Study Procedures
If you agree to be in this study, you will be asked to sign and date this consent form. You will undergo the following tests and procedures to determine if you are eligible to participate in this study.

- 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.
- You must pass a screening physical prior to the start of the study.

- You will have blood samples drawn to look at the biochemical in your blood.
- If you are a woman who could possible become pregnant, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study.
- You may be tested for COVID-19 1-2 days prior to the experimental day. The experiment will be postponed if you test positive.
- You will be shown, and asked to practice the Multi-Attribute Task Battery II (MATB-II) test so that you can perform it easily and accurately to achieve your very best scores before you begin the actual testing under the experimental conditions. The MATB-II is a test developed by NASA where you will be asked to pilot a vehicle on a straight course while analyzing and reacting to a variety of other distracting signals on the computer screen. The test will record your speed and accuracy at performing the task. With all performance tests like the MATB-II, people go through a learning process during which they become proficient and can eventually do the test equally well on repeated occasions.
- You will undergo training on the equipment to be used including the breathing system, immersion tank, and cycle ergometer, to ensure you will be able to use the equipment on the study day. During the investigational session, you will breathe from a specialized breathing circuit, consisting of a mouthpiece, hoses, valves and bags. The breathing apparatus will allow measurement of exhaled oxygen and carbon dioxide, pressure at the mouth, breathing rate and volume, and consumption rate of oxygen.
- You will have an electrocardiogram (EKG) performed looking at your heart's electrical activity.
- You will perform a breathing test to check your normal lung function. This involves blowing forcefully into a machine and does not normally cause any discomfort.
- You will perform a maximal exercise test "VO2max" on a stationary bicycle while breathing through a mouth piece and a specialized breathing circuit. This normally causes fatigue and mild leg muscle soreness.
- If you have not been inside a hyperbaric chamber and have not been SCUBA diving in the past, you will have a chance to do a "pressure test" in the chamber to make sure you are comfortable with the increased pressure, and learn how to equalize the pressure in your ears.

If you are eligible to participate in this study, you will be randomly assigned (like drawing numbers from a hat) to the order in which you will receive the ketogenic food products or placebo for each of the two experiments.

Study procedures

- The night before the experiment, you be asked not to eat after dinner (around 8 pm).
- On the experimental day, you will be asked not to eat breakfast or consume any caffeine before coming to the lab. You will arrive at the laboratory at a designated time in the morning. You will be given breakfast bars or shake for breakfast.
- Vital signs will be taken.

- Females will have a urine pregnancy test.
- You will again practice the MATB-II test until you are as good as possible before going into the pressure chamber.
- You will have electroencephalogram (EEG) electrodes attached to your scalp with paste and tape which can be washed out later. This allows us to monitor and record your brain waves during the experiment.
- You will have electrodes placed on your fingers and forehead which detects small electrical activity through your sweat glands. This is called "electrodermal activity" monitoring or EDA. This is painless and similar to an electrocardiogram (EKG).
- You will have an intravenous catheter placed for collecting blood samples. Baseline blood samples will be drawn for clinical testing and measurement of ketones in your blood.
- For one of the two experiments you will consume ketogenic food products to help boost your ketone levels and provide extra energy for the experiment. Participants will consume the ketone food products three times, 30 minutes apart.
    - The ketogenic food products are made up of three components. The first two are mixed together in water and consumed as a "shake": ketone salts, primarily beta-hydroxybutyrate, a ketone that is naturally occurring in the body, which will help raise your body's ketone levels prior to the experiment and provide energy. The second part of the shake is a "medium chain triglyceride" which is a form of fat that your body can use as fuel during exercise. You will only drink this shake only once.
    - The third food product is a "ketone diester" of beta-hydroxybutyrate and acetoacetate which are also naturally occurring in the body and also help raise your body's ketone levels. Because the ketone diester liquid does not taste good, the liquid has been placed in "gel-caps" so you can drink this like a pill without needing to taste the liquid. Each person will consume gel-caps three times, 30 minutes apart. The food products are commercially available from vendors on-line or at stores.
- You will then enter the hyperbaric chamber and climb into the pool where you will be immersed in 82 degree Fahrenheit water only to your shoulder level. The safety diver will be in the pool with you, helping to set up the equipment. Once seated, you will practice the MATB-II one more time while pedaling lightly on the exercise bike.
- Once all equipment is set up, the chamber will be pressurized with air to the equivalent of 35 feet below the surface of the ocean.
- Once at this depth, you will begin breathing 100% oxygen through a mouthpiece, begin pedaling the exercise bike (equivalent to a light jog), and perform the MATB-II test. Breathing through the mouthpiece allows us to measure exhaled oxygen and carbon dioxide, pressure at the mouth, breathing rate and volume, and consumption rate of oxygen.
- The hyperbaric portion of the protocol will take between 30 minutes to 2 hours. The time range is large because great variability of the time to presentation of symptoms has been seen in both the repeated exposures of individual subjects and between different subjects with similar exposures.

- Blood samples will be taken from your catheter before starting and every 20 minutes thereafter, and immediately when the study ends. These samples will be used to measure ketone levels and compare the levels of CO_2 in your blood to the amount of CO_2 in the gas you exhale from your lungs, $PETCO_2$. The maximum amount of blood drawn during any one experiment will be approximately 50 ml which is about 3.5 tablespoons.
- Breath acetone will be measured before and after the experiment by breathing out into a small handheld device.
- You will notify the safety diver immediately when you experience any symptoms. The Safety diver will stop the study immediately if he or she notices any signs of oxygen toxicity, confusion (or change in your mental status), twitching or difficulty concentrating. The researchers outside the chamber will stop the study immediately if they see changes in your brain waves (EEG), any signs of oxygen toxicity, or poor performance on the MATB-II.
- After the chamber comes to the surface, you will perform a final MATB-II test, and have a final blood sample collected. The catheter removed from your arm.

Over the course of this study, you will receive both a ketogenic food product and placebo, just the order in which you receive them will differ. You will not be told which (food product or placebo) you are receiving on either experimental day. You will be monitored for any side effects of the food products, placebo and the hyperbaric chamber experiment.

HOW LONG WILL I BE IN THIS STUDY?
From the day of enrollment to the end of study will take approximately 2-4 weeks. The pre-study session described earlier will generally require 4-5 hours. Training will be performed to maximize each subject's performance on the investigational apparatus, and may require some additional training on an individual basis (between one and five hours). Each test day will require approximately 6 hours.

WHAT ARE THE RISKS OF THE STUDY?
Most Likely:

- Risks associated with drawing blood from your arm: These risks are momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.
- Pain associated with catheter placement: Placement of this catheter will be performed after injection of local anesthetic (numbing medicine) and is not normally associated with major discomfort, but pain can result.
- Risks associated with breathing high levels of O_2 (oxygen toxicity):
    - The most common symptoms and risks from O_2 exposure include: vision disturbances, ear-ringing, nausea, twitching, tingling, irritability, dizziness, poor concentration, difficulty speaking, loss of consciousness or seizure. There will be a safety diver and at least one other staff member in the chamber with you at all times. The safety diver will be in the water with you (less than an arms-length away), watching closely for any signs or symptoms mentioned above. The safety diver and the staff in the chamber will

immediately assist you if any symptoms arise. You will be instructed to spit out the mouthpiece (stop breathing oxygen) and stop pedaling the bike as soon as you experience any symptoms, and the experiment will end.. You will be asked to describe what you are experiencing and continue playing the MATB-II simulator.

- Having a seizure is a risk of breathing the high oxygen levels in this study, but least likely to occur compared with other symptoms of oxygen toxicity above. In general, seizures can cause sore muscles, and may result tongue biting or bruising to the body. You will be seated for the experiment with your head out of the water and secured into a harness. This will help prevent injury and help prevent your head from going under water in the event of a seizure, which could lead to injury such as water going into the lungs causing drowning or lung infection. Staff have been trained to manage seizures in the chamber, will be within arms reach of you for the entire experiment and you will be secured in the harness to keep your head out of the water. Seizures are rare in hyperbaric oxygen treatments, but are a known side effect usually stop after the oxygen is removed. No permanent side effects have been documented in humans as a result of oxygen seizures, but you could have a period of confusion and headache afterward. This usually gets better in 5 to 30 minutes. In a past study using the same dive protocol, one seizure happened out of 95 dives and there was no injury or lasting effects.

- Risks associated with consuming the ketogenic food products: Mild nausea, vomiting, diarrhea, abdominal cramps, mild intermittent constipation (difficulty moving your bowels), and mild intermittent hunger were mentioned by subjects in other studies. Our study is revealing the same side effects in some subjects. The most common reported side effect in the first phase of our study was hunger, which resolved when eating after the study was over. This phase of the study should be shorter in duration than the first. Other side effects experienced included: stomach cramps and/or nausea (mild, except for one subject which required anti-nausea medicine), one episode of diarrhea in a subject after the study was over and 2 episodes of diarrhea during the study day in another subject. Mild/moderate levels of headache, hunger, fatigue, lightheadedness, difficulty focusing were also reported.

Possible:

- Risks associated with compression or increasing the air pressure inside the chambers (simulation of depths beneath the sea): With compression there is occasional difficulty getting the air pressure in the ears, sinuses and teeth to equalize to the increasing pressure outside the body. Such problems may cause pain and the production of fluid in these spaces. Hearing loss or inflammation of the ear or sinuses may occur. Usually, these problems are temporary and clear in a few days. Very rarely permanent problems occur. However, if any discomfort is felt during compression, the person with you in the chamber should be immediately notified so that corrective measures can be taken. If you have not been at increased pressure before (such as in the hyperbaric chamber or SCUBA diving), you will have a chance to practice this during the screening day to make sure you are comfortable and not having any problems.

Less likely:

- Risks associated with catheter placement: Infection and allergic reaction to the local anesthetic. Other risks include damage to the vein that the catheter is being put through or clot formation in the vein which usually gets better in a few days.
- Risks associated with compression or increasing the air pressure inside the chambers: In this experiment the hyperbaric chamber will be used to simulate an atmospheric pressure reached in the water during Navy diving activities. The risks of hyperbaric chamber dives is similar to that of actual in-water diving and includes a collapsed lung (pneumothorax), decompression sickness (DCS) and arterial gas embolism (AGE).
    - Risk of pneumothorax: Rarely some individuals have air filled cysts in their lungs. If such a person is exposed to increased pressure, the cyst could possibly rupture and cause the lung to collapse, requiring medical and/or surgical treatment such as inserting a tube through the skin into the chest to re-expand the collapsed lung. This complication is extremely rare and it almost always occurs in people with lung disease.
    - Risk of decompression sickness (DCS): Because you will be breathing 100% oxygen during the experiment, there is essentially no risk for decompression sickness (DCS). This experiment will strictly follow the US Navy diving protocols regarding the depths and times of the hyperbaric chamber dives. The risk of DCS is estimated to be 1 to 2 per 10,000 dives. The symptoms of DCS are usually pain in a muscle or a joint, skin rash, numbness or tingling in part of the body. However, severe cases of DCS can cause weakness in the arms or legs, difficulties with hearing, difficulties with balance, difficulties with urination and defecation, problems with thinking and memory, paralysis and even death. However, severe cases of DCS are much less common than mild cases and because we will follow the Navy protocols the risk of any type of DCS is very low. In addition, most, but not all, cases of DCS can be successfully treated by prompt recompression with hyperbaric oxygen, a therapy that is immediately available at the same facility where the experiment is taking place.
    - Risk of arterial gas embolism (AGE): Under some unusual diving circumstances such as when a diver holds his breath while ascending, lung air sacs may rupture releasing gas bubbles into the chest, neck and blood. The gas bubbles may travel through the arteries and cause a blockage of blood flow to the heart, brain other organs and a heart attack or stroke may occur. Because the speed of the change in depth is always controlled and monitored by the hyperbaric chamber operators, AGE is much less common in chamber exposures than in actual in-water dives. Like in DCS, most, but not all, cases of AGE can be successfully treated by prompt recompression with hyperbaric oxygen. This treatment is immediately available at the same location where you are participating in the experiment.
    - Other risks associated with exposures to increased atmospheric pressures (simulated depths beneath the sea): An additional potential risk associated with exposure to increased atmospheric pressure is destruction of certain parts of long bones (bone necrosis). Experts generally agree that this problem is exceedingly rare with exposures to

simulated depths of less than 150 feet and/or for exposure times not exceeding three to four hours. During this experiment you will be breathing 100% oxygen, which has never been associated with bone necrosis.

- 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 chambers have a very good safety record. 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.
    - a fire that occurred during an animal study that caused no injury to humans conducting the experiment. As a result, all new equipment is subjected to evaluation and testing before its use for all in chamber systems.

  In over 30 years of operation, there have been no instances of serious structural failure.

Drug and Food Interactions
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

For Those of Reproductive Potential
For women: Pregnancy affects how your body handles food, and could affect the study results. In addition, the effects of the ketogenic food products on a developing pregnancy are not known. If you could possibly become pregnant, pregnancy tests will be done at the pre-study visit and laboratory visit as described above. Although there is no risk to a pregnancy between the pre-study visit and laboratory visit, if you become pregnant between visits you will not be able to continue in the study. You should either abstain completely from vaginal intercourse during the study or use an effective method of birth control until the last study visit.

General Risks: It is important that individuals about to undergo tests involving a changing of atmospheric pressures understand that there may be risks which are unknown. Investigators will answer any questions that you have regarding this research.

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

PHYSICIAN AVAILABILITY
A doctor experienced with hyperbaric medicine is available before, during, and after the test. This includes initial medical screening and a pre-test physical to ensure 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
There will not be any direct benefits to you if you decide to participate in this research project. However, your participation with the project may help researchers to better understand how to use the ketogenic diet to improve the safety of divers and military personnel.

ARE THERE ANY RESTRICTIONS ON MY ACTIVITIES BEFORE OR AFTER THE STUDY?
You may not participate in any other diving 48 hours before or flying or diving 48 hours after the study. You will be asked not to eat after dinner (7 pm) the night before the study.

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.

All of these tests are being done only because you are in this study. As part of the study, Dr. Derrick and his study team will report the results of your study-related tests to the U.S. Navy. Study data which may include subject number, age, study date/time, blood sample values, body measurements like height and weight, oxygen toxicity symptoms, and monitoring measurements recorded during the study like EKG, EEG, EDA, and heart/breathing rhythm tracings, may be shared with Dr. Dominic D'Agostino at the University of South Florida, Drs. Ki Chon and Hugo Posada-Quintero at the University of Connecticut, and Dr. Xavier Vrijdag and doctoral student Lachlan Barnes from the University of Auckland for additional analysis. No other personally identifiable information such as your name or date of birth will be shared.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, the U.S. Navy, and/or the Duke University

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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.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research will be destroyed or information identifying you will be removed from the study results at DUHS.

This information may be further disclosed by the sponsor of this study, the U.S. Navy. If disclosed by the sponsor, the information is no longer covered by the federal privacy regulations. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

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.

Your 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. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

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.

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. You may participate in the study, without allowing your photograph to be taken.

_____ "Yes, I agree to be photographed."

_____ "No, I do not agree to be photographed."

Video of the study is recorded as part of the EEG to assist the neurologist with interpretation. You will be asked if you agree to be recorded before any recording. If recorded, such recordings might be

presented at meetings describing the research, in which case a bar or blurring will be placed over the area of your eyes to make the recording less identifiable. You will not be identified nor will your individual results be discussed in such cases without your permission.

Please read the sentence below and put your subject initial next to your choice. You may participate in the study, without allowing your video to be taken.

_____ "Yes, I agree to be video recorded."

_____ "No, I do not agree to be video recorded."

All of the blood studies are being done only because you are in this study. The study results will not be given to you or sent to your physician unless, in the opinion of one of the study physicians, information important to your future health is learned.

WHAT ARE THE COSTS?
There are no costs to you for participating in this research project.

WHAT ABOUT COMPENSATION?
You will be compensated for participating in this study. You will receive $50 after completion of the initial screening visit. You will receive $300 for completion of each of the experimental sessions.

The collection of your social security number by the Duke study team is required in order to set up payment. Payment received as compensation for participation in research is considered taxable income to the research subject. If payment to an individual exceeds $600 in any one calendar year, Duke University is required to report this information to the Internal Revenue Service (IRS). Research subject payments to a non-employee of Duke University exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the IRS.

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., your Duke physicians or the study sponsor, the Office of Naval Research, 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. Bruce Derrick at (919) 684-6726 during regular business hours and at his cell phone (315) 440-2565 or pager (919) 970-9792 after hours and on weekends and holidays.

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WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
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. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal), but you must do this in writing. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be kept on file by the study doctor.

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. 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. If you do decide to withdraw, we ask that you contact Dr. Derrick in writing and let him know that you are withdrawing from the study. His mailing address is: DUMC Box 3823 Duke University Medical Center, Durham, NC 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

Your study doctor may also decide to take you off this study if you have serious side effects, or if your study doctor determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include your inability to equalize the pressure in your middle ears during a hyperbaric chamber dive, a problem with a venous or arterial catheter or if the sponsor decides to discontinue the study.

Your samples and/or 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. If 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 data and samples may result in commercial profit. You will not be compensated for the use of your data and samples other than what is described in this consent form.

A description of this clinical trial will be available on http://www.ClinicalTrials.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.

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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 or suggestions about the research, contact Dr. Bruce Derrick at (919) 684-6726 during regular business hours and at his cell phone (315) 440-2565 or pager (919) 970-9792 after hours and on weekends and holidays.

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.

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