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Duke University Health System

Consent to Participate in a Research Study
NASA Prebreathe Study
IRB #Pro00116846

KEY INFORMATION SUMMARY

The aim of this study is to increase the safety of astronauts performing extravehicular activities (EVAs), which consist of "spacewalks" in spacesuits outside the International Space Station, or in the future on the moon. When astronauts move outside the space station in a spacesuit there is a decrease in atmospheric pressure of approximately 70%. This carries the risk of generating nitrogen bubbles in the body, which can cause decompression sickness. To reduce that risk, before exiting the station, astronauts breathe 100% oxygen ("prebreathe") for several hours. The optimal time for the prebreathe is not known. This study is validating techniques to assess the effectiveness of future prebreathe protocols.

If you volunteer for the study you will be examined for eligibility, exercise tested and trained for the various exercises used in the study. During the test day you will prebreathe oxygen for 6½ hours, after which you will be decompressed in the Duke altitude chamber to a pressure equal to that of the spacesuit during an EVA. While in the chamber you will perform light exercise and undergo ultrasound examinations to test for bubbles. The duration of the study will be 4 days (approximately 27 hours based on time commitment per day).

The major risk of the study is development of decompression sickness (DCS). The most common symptoms of DCS are pain in the arms or legs and skin rash, however more serious symptoms such as arm or leg weakness can occasionally occur. If you develop symptoms suggesting DCS you will immediately be removed from the chamber, examined and treated. You can also leave the study voluntarily at any time.

Research studies are voluntary. You do not have to agree to be in this study. Please read this consent form carefully and take your time making your decision. The study team will discuss the study with you. Please ask about 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

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important information about the study are listed below and will be reviewed with you by the study team.

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

Dr. Richard Moon will conduct the study. The study is funded by a grant from the National Aeronautics and Space Administration (NASA). Portions of Dr. Moon's and the research team's salaries will be paid by this grant.

Why is this study being done?
The purpose of this study is to test and validate a method of simulating the conditions and kinds of activities that astronauts perform during EVA.

Up to 30 people will take part in this study at Duke.

What is involved in the study?
Screening (Day 1 – approximately half a day): First you will be screened to ensure you are eligible for the study. This will include a physical exam, maximum exercise test on a stationary bicycle and a cardiac echocardiogram to check for an opening between the right and left side of your heart. A test called an echocardiogram uses sound waves (ultrasound) to outline the structure of the heart. Bubble contrast echocardiogram uses a small intravenous injection of salt solution mixed with tiny air bubbles (contrast agent) to improve the visualization of blood flow within the heart during an ultrasound exam. The purpose of this test is to detect a hole in the heart (atrial septal defect) that could increase the risk of doing this study. If you have an atrial septal defect you would not be eligible for the study.

Calibration (Familiarization) Session (Day 2 – 2 to 3 hours): Following screening, you will participate in a familiarization session during which you will receive a description of the test protocol and be encouraged to ask questions. Then, you will be familiarized with the chamber protocol and safety procedures. Your metabolic rate (how fast your body burns energy) will be measured while performing arm and stepping exercises (low to moderate exercise). These exercises will be (1) step up and down on steps 6 and 12 inches high at a set cadence; (2) transfer a weight (15 and 25 pounds) from one location to another; (3) arm ergometry (moving a set of pedals with your hands at a specific rate); (4) perform fine motor skills with your hands while kneeling down; (5) use hand tools and perform hand movements while standing.

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Practice Day (Day 3 – 4 to 6 hours): This will involve 'rehearsal' with other subjects of the procedures to be performed on the Test Day while wearing the breathing equipment to be used during the time at altitude.

Test Day (Day 3 – 13 to 14 hours): You will first breathe 100% oxygen using a transparent hyperbaric hood for 6½ hours. This will be followed by 6 hours in an altitude chamber, a cylindrical compartment 17 ft long, 10 ft high in which air pressure can be reduced to simulate 30,000 feet altitude. During this time you will periodically perform the exercises listed above, and undergo periodic ultrasound monitoring of your heart. In each cycle you will perform 15 minutes of low- to moderate-intensity exercise followed by 5 minutes of monitoring and rest. You will also be asked regularly if you have any symptoms that suggest decompression sickness. If you do have symptoms you will be removed from the chamber, assessed by a physician and if decompression sickness is confirmed, will be treated for it.

During the 6 hours at altitude there will be continuous video recording of the study inside the altitude chamber. This video will be sent to the sponsor (NASA). Your face may be recognizable in the video.

Will I be given research results that may affect my medical care?
Results of this research relevant to your health will be communicated to you.

How long will I be in this study?
The study will require a 4 day time commitment (approximately 27 hours over 4 days based on time commitment per day as outlined above).

You can stop participating at any time without penalty.

What are the risks 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 of decompression sickness (DCS). You may develop signs or symptoms of DCS as a result of the altitude exposure. DCS symptoms are due to gas bubbles forming in tissues and blood. The most common symptoms are usually 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, blurred vision, dizziness, hearing

loss, tingling, numbness, weakness, extreme 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 low. We will monitor you for the presence of bubbles in the veins and arteries using ultrasound. You will be removed from the experiment if arterial bubbles are found even if no symptoms of decompression sickness develop.

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 this study 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.

2. Barotrauma. With compression (returning from altitude to ground level) 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. Lung injury. During decompression, lung air sacs may rupture resulting in gas bubbles occurring in the chest, neck and blood. The gas bubbles may travel through the arteries and cause a blockage of the arteries supplying the heart, brain or other organs. A heart attack or stroke may occur. This problem is termed air embolism; it is rarely encountered in chamber exposures and has not been seen in the Duke chambers.

You will be monitored constantly during the research study activities, and there will be medical staff available at all times who are prepared to treat as soon as symptoms are recognized. It is common to experience some shortness of breath or cough with exercise and exposure to high altitude, but should your symptoms

become concerning to you, you are free to stop the experiment for treatment at any time.

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 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 hyperbaric 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 nearly 60 years of operation, there have been no instances of serious structural failure.

3. Risks associated with a maximal exercise test. The bicycle test you will be asked to perform as part of screening is a graded VO2 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 test is stopped 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.

4. Risks to an unborn child. Because the changes your body goes through during pregnancy may affect study results, and exposure to the hypobaric chamber may affect the risks of a pregnancy complication, people who are pregnant are not allowed to participate in this study. You will be asked a series of questions about your risk of pregnancy both at your screening visit and on the day of your study, and a urine pregnancy test will be performed if your answers suggest that you may be pregnant. If the pregnancy test is positive, you will not be allowed to continue with the study. You should use appropriate birth control between your screening visit and study visit to minimize the chances you will not be able to complete the study.

5. Risks of injection of bubble contrast for the echo study. Injection may have mild side effects such as flushing, warmth, or a brief feeling of discomfort at the injection site. There could also be bruising or discomfort. Although very rare, allergic reactions can occur from the contrast agent.

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

Drug and Food Interactions: For your safety, you must tell us about all the medications and supplements you are taking. These may include prescription drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and medical foods 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.

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.

Are there benefits to taking part in the study?
If you agree to take part in this study, there is no direct medical benefit to you. We hope that in the future the information learned from this study will benefit astronauts.

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.

As part of the study, results of any study-related tests or procedures will be shared with NASA and its affiliates without your personal identity. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include:

- representatives and affiliates of NASA
- the Duke University Health System Institutional Review Board

If any of these groups review your research record, they may also need to review your entire medical record.

Ultrasound images without your personal identity will also be shared with an investigator on this project based at the University of North Carolina. All of the procedures are being done only because you are in this study. The study results will not be provided to you OR sent to your personal healthcare provider unless you request them.

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 information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study or to outside reviewers for audit purposes. If disclosed by the sponsor or outside reviewers, the information is no longer covered by federal privacy regulations.

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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.

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 confidential. If you decide to share your 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.

As part of this study, you will have echo imaging and continuous video recording. For the tests to be useful, limited identifiers like test dates and date of birth are necessary. By signing this consent form, you authorize Dr. Moon to send these specific identifiers in the images to NASA and their designated affiliates.

Representatives from NASA and/or University of North Carolina may be present at certain study visits/procedures.

Will it cost me anything to be in the study?
There are no additional costs to you for participating in this study. You and your insurance company will not be billed for your participation.

Will I be paid to be in the study?
You will receive $50 for screening (Day 1). If you are eligible and participate in the study you will receive $150 for Day 2, $200 for Day 3, and $600 for Day 4.

If all 4 study sessions are completed, total compensation is $1,000. In order to issue your payment, Duke University may need to collect your name, mailing address, and social security number for tax reporting purposes. If you do not want to provide this information, you cannot be paid but you can still take part in the research study.

Payment received as compensation for participation in research is considered taxable income to the research participant. Research participant payments to a non-employee of Duke University adding up to $600 or more during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the individual and a copy sent to the Internal Revenue Service (IRS).

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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 except for treatment of decompression sickness, for which the expenses will be paid by the sponsor.

For questions about the study or research-related injury, contact Dr. Richard Moon at 919-684-8111, pager ID #970-5290 during regular business hours or after hours and on weekends and holidays.

What if I want to withdraw from the study?
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 sent to the funder of this study.

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 withdraw from the research we ask that you honor any requested follow-up visits. If you do decide to withdraw, we ask that you contact Dr. Moon in writing and let him know that you are withdrawing from the study. His address is Box 3094, 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.

The use of your data 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 https://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 should 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, contact Dr. Moon at 919-684-8111, pager ID #970-5290 during regular business hours or after hours and on weekends and holidays.

You can call the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111 if:

- You have question about your rights as a research participant
- You wish to discuss problems related to the research
- You have any concerns or suggestions related to the research
- Want to obtain information or offer input about the research

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 Participant	Date	Time
Signature of Person Obtaining Consent	Date	Time