Participant Name:_____Date:_____

Title of Study: Improving exercise capacity in chronic obstructive pulmonary disease patients through uphill walking

Principal Investigator: Debra Romberger, MD VA Facility: **NWIHCS**

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study about chronic obstructive pulmonary disease and pulmonary rehabilitation. **Chronic obstructive pulmonary disease or COPD is term that describes a lung condition that makes people short of breath, especially with activity. Both emphysema and chronic bronchitis are forms of COPD.** Typically, during pulmonary rehabilitation, exercise becomes more difficult as the speed is increased. However, our research indicates that increasing speed may limit the amount of time one can exercise. This study will compare walking faster versus walking up a slight incline to see which leads to less breathlessness. It is being funded by the Department of Veterans Affairs. By doing this study, we hope to learn more information about exercise in COPD that may lead to improvements in rehabilitation.

The purpose is to understand how walking uphill affects your breathing and how you perceive your breathlessness. We will compare uphill walking to walking on flat ground but faster. You will be asked several questions about your medical history and you'll be asked to do a breathing function test.

WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will last about one month and include five visits at three sites.

VISIT 1: If you agree to participate, you will be asked questions about your medical history and to undergo a breathing test to test your lung function at the VA. This visit may take up to 1 hour.

VISIT 2: If you meet the initial criteria, you'll be asked to go to Nebraska Medicine and participate in a cardiopulmonary exercise test. This test is designed to have you walk until you cannot go further. A physician and nurses will supervise you while you participate in the test. This visit could take up to 1½ hours. The physician then reads your test and determines if you have any underlying heart issues. If you do, they will refer you to speak with your personal physician.

VISIT 3-5: If you do not have any underlying conditions that would prevent you from participation, you'll be asked to go to UNO three more times. Each of these visits could take up to 1½ hours.

In all, there is one visit to the VA, one visit to Nebraska Medicine, and three visits to UNO over the course of up to one month.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

You are not expected to get any benefit from being in this research study. The information we may get from this study will help us design future studies that will focus on new procedures for rehabilitation.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

Potential risks of this study are no more than would be involved during normal physical activity, such as shortness of breath, fatigue, and muscle soreness are possible in this study. Due to your COPD, dynamic hyperinflation (air trapping) you may feel breathless. The risks of the cardiopulmonary exercise test are a slight risk of a serious cardiac event or death. You may find answering some of the questionnaires as uncomfortable as they ask questions regarding quality of life and how COPD affects your daily life. Loss of confidentiality is also a potential risk. It is possible that other rare side effects could occur which are not described in this consent form. It is also possible that you could have a side effect that has not occurred before.

The alternative to participating in this study is not to participate. You could speak with your physician about a cardiopulmonary exercise test or pulmonary rehabilitation.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Debra Romberger of the VA Nebraska-Western Iowa Health Care System (VA NWIHCS). If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is

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RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn how walking uphill affects your breathing and how you perceive your breathlessness. We will compare uphill walking to walking on flat ground but faster. Currently, many rehabilitation programs increase the speed of a treadmill or bicycle to increase the intensity of exercise; however, this can make some patients very short of breath. This study will see if walking uphill, but slower, will increase the intensity of exercise and help patients maintain comfortable breathing.

HOW LONG WILL I BE IN THE STUDY?

A total of 25 subjects will participate in this study. This research study is expected to take approximately one month. Your individual participation in the project will take a total of five visits within that one month. The first visit is to the VA Clinical Research Unit. The second to Nebraska Medicine. The last three are at UNO.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

VISIT 1 at the VA:
If you agree to participate, you will be asked questions about your medical history and to undergo a breathing test to test your lung function. You will be asked to complete questionnaires about COPD and how it affects you. You are free to skip any questions that you would prefer not to answer. This visit may take 1 hour.

VISIT 2 at Nebraska Medicine:
If you meet the initial criteria, you'll be asked to go to the medical center and participate in a cardiopulmonary exercise test. This test is designed to have you walk until you cannot go further. A physician and nurses will supervise you while you participate in the test. The physician then reads your test and determines if you have any underlying heart issues. If you do, they will refer you to speak with your personal physician. This visit may take up to 1½ hours.

VISTS 3-5 at UNO:
If you do not have any underlying conditions that would prevent you from participation, you'll be asked to go to UNO three more times.

Visit 3 at UNO:
You will complete four questionnaires about your COPD and your quality of life. You will then be asked to find your preferred walking speed on the treadmill. After we find your preferred walking speed, you will rest for a long period of time until your heart rate and breathing return to normal. You will then walk on the treadmill, slower than your preferred walking speed but starting with an incline, and the treadmill incline will be increased every minute for up to 10 minutes. You will again rest for a long period of time until your heart rate and breathing return to normal. Next, you will walk on the treadmill slightly faster than your preferred walking speed and the treadmill will be flat. The speed will be increased slightly every minute for up to 10 minutes. The combination of speed and slope will be recorded for a future visit. You will be asked to wear a mask over your mouth and nose but will still be able to breathe normally. This visit may take up to 1½ hours.

Visit 4 at UNO:
Within 10 working days, you will return to UNO. We will have you wear a form-fitting suit like a wrestling singlet. We will place small "markers" on your back, chest, stomach, legs, hips, and pelvis. These are small, styrofoam balls that are covered in a reflective material. They will be taped to your body. You will then be asked to do a breathing test while seated. Once that is complete, you will walk on the treadmill for up to 10 minutes either starting at an incline or flat based on the speeds we determined in visit 3. Immediately at the end of walking we will ask you to repeat the breathing test and ask you several questions about your effort to breathe, how heavy your legs are, and so forth. This visit should take up to 1½ hour.

Visit 5 at UNO:
Within 10 working days, you'll return to UNO. This visit is like Visit 4 but you'll be asked to walk on the treadmill starting at an incline or flat; which ever you did not do in Visit 4. This visit should take up to 1½ hour.

All of the things you will be asked to do are for research purposes only.

While you participate in this research, it is important that you:

- Keep your study appointments. If you miss an appointment, please contact us to reschedule as soon as you know you will miss the appointment.
- Tell usif you believe you might be pregnant.
- Ask questions as you think of them.

While participating in this research study, do not take part in any other research project without approval from the investigators. This is to protect you from possible injury from things such as extra pulmonary testing. Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Screening:
You may find answering some of the questionnaires as uncomfortable as they ask questions regarding quality of life and how COPD it affects your daily life. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

Cardiopulmonary exercise test:
The risks of the cardiopulmonary exercise test are similar to the experimental risks; however, there is a slight risk of a serious cardiac event or death. The risk of dying from cardiopulmonary exercise tests is rare; the risk was of 0.5 per 10,000 tests. A major cardiac event during cardiopulmonary exercise test is also a rare circumstance, with a reported event rate of 1.2 events per 10,000 tests. The cardiopulmonary exercise test will be administered in the hospital under the direction of medical professionals, including a physician. All safety precautions will be in place, including a crash cart.

Walking trials:
Common risks of the walking faster or uphill are no more than would be involved during normal physical activity, such as shortness of breath, fatigue, and muscle soreness. Air trapping leading to breathlessness may also be a risk to participation. You will only be asked to participate in the walking trials if a physician has cleared you to participate after the cardiopulmonary exercise test. You will be able to stop the walking trials at any time allowing you to stop before you become too breathless. You will be asked to rest until your breathing rate and heart rate return to resting levels, or up to one hour. If there is a serious problem while you are at UNO, all staff within the Biomechanics Research Building are certified in basic life support and the use of automatic external defibrillators (available on site). We also have immediate access to certified emergency care responders in the building connected to ours.

Breathing tests:
Risks of breathing tests are rare and non-life-threatening, such as light-headedness, dizziness, or minor chest pain. If you feel any of these symptoms, you can stop the breathing tests at any time.

Other:
There are no known social and cultural risks to participation. There are no financial risks to participation within this study. The potential breach of confidentiality with research records is a known risk. Your information will be coded to protect your identity. Only members of the research team will have access to this data and information. Loss of confidentiality may result in psychological or social harm.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There are no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help others with your conditions.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

In the course of this study we will collect information about you. The information may include things that could be used to find out who you are (like your name, phone number, birthdate, address, and medical record number). This is called identifiable private information. We also will collect medical information about you (like medical record number, medical history, or the results of physical exams, cardiopulmonary exercise tests, or other medical or research procedures). This is called "protected health information" or PHI. PHI is protected by a Federal Law called the HIPAA Privacy Rule. We will collect only the minimum amount of PHI that we can. During and after the research we will keep your PHI as confidential as possible. During and after the research we will keep your research records as confidential as possible. Your data will be stored in a secure location either electronically or in hard copy.

Identifiers might be removed from the identifiable private information collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will include information about your study participation in your medical record.

Incidental findings (such as a cardiac problem) from the screening process will be handled through Omaha VAMC. If a finding is made, especially during the cardiopulmonary exercise test, the physician overseeing the test will inform you of the findings and provide you a course of action. Findings that impact medical care will be documented by the physician in your electronic medical record.

The Omaha VA Institutional Review Board (IRB) Institutional officials designated by the VA IRB may review your data. Federal law requires that your information may be shared with these groups: The HHS Office of Human Research Protections (OHRP) and the Department of Veterans Affairs.

You are authorizing us to use and disclose your PHI for as long as the research study is being conducted. You may cancel your authorization for further collection of PHI for use in this research at any time by contacting the principal investigator in writing. However, the PHI which is included in the research data obtained to date may still be used. If you cancel this authorization, you will no longer be able to participate in this research.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

Financial Compensation:
You may be compensated up to $100 for participation in this study for your time. No pay is offered for the screening visit and cardiopulmonary exercise test. If you are enrolled into the study, you will receive $20 for the first visit to the laboratory and $40 each for the second and third visits to the laboratory. Payments will be disbursed at each visit and can been collected at the VA Cashiering Office with the approved form. If you decide to withdraw or are withdrawn from the study, you will be paid the pro-rated amount according to your participation.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

No compensation is available to you should an injury occur. The VA will provide treatment for research related injury in accordance with applicable federal regulations (38 CFR 17.85).

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING THE DAY:

Dr. Debra Romberger at 402-554-7539 and

AFTER HOURS:

Dr. Debra Romberger at 402-554-7539 .

Emergency and ongoing medical treatment will be provided as needed.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this study is voluntary. You can decide not to be in this research study. Deciding not to be in this research will not affect your relationship with the investigator or the VA.

You can stop participating in this research (withdraw) at any time by contacting the Principal Investigator or any of the research staff. Deciding to withdraw will otherwise not affect your care or your relationship with the investigator or this institution. You will not lose any benefits to which you are entitled.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

You may be taken off the study if you do not follow instructions of the investigator or the research team. You may also be taken off the study if you

- fall and injure yourself
- have any other medical emergency (for example, chest pain, extreme breathlessness beyond what you normally experience)
- have a breathing attack during the visit requiring the use of your rescue inhaler

Any research data obtained to date may still be used in the research

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions at any time about this study, you should contact the Principal Investigator or any of the study personnel listed on this consent form or any other documents that you have been given.

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Jodi Wilson
402-995-3477

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Research Administrative Officer at 402-995-3541 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

FUTURE USE OF DATA AND RE-CONTACT

If you would like to be contacted regarding future research studies, please indicate below.

_____Yes, I would like to be contacted about future research studies.

_____No, I do not want to be contacted about future research studies.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____has explained the research study to me. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this document below, I voluntarily consent to participate in this. I also confirm that I have read this consent, or it has been read to me. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name (Print)	_____ Participant's Signature	_____ Date

Identification of Person Obtaining Consent.		
_____ Name of Person (Print)	_____ Signature of Person	_____ Date