Wake Forest®
School of Medicine

Department of Internal Medicine
Section of Pulmonary, Critical Care Medicine

A STUDY TO PROMOTE CRITICAL ILLNESS RECOVERY IN THE ELDERLY

Informed Consent Form to Participate in Research
Rita Bakhru, MD, MS: Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have respiratory failure requiring mechanical ventilation. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test the safety and effects of starting physical therapy early (including physical therapy (PT) and the in-bed cycle) compared to normal. Other studies have looked at early physical therapy and some have found benefit to it; none have found harm. We would like to look at the effect of early physical therapy including the use of an in-bed cycle as we think the in-bed cycler would allow more PT earlier.

The Motomed Letto 2 Cycle Ergometer has been approved by the US Food and Drug Administration (FDA) for use in patients.

In this study, early physical therapy will be compared to normal physical therapy. In this study you will either receive early physical therapy OR normal physical therapy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

42 people total will take part in this study. All will be at Wake Forest.

WHAT IS INVOLVED IN THE STUDY?

Once you decide that you want to participate, you will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have 1 chance out of 2 that you will receive early physical therapy.

The testing personnel will not know which group you will be placed into. This is done so that a fair evaluation of results can be made. This information is available to the researchers if needed in an emergency.

Group 1: Early Physical Therapy
You will receive early physical therapy (both with the in-bed cycler and regular physical therapy) as soon as it is deemed safe. Most participants will receive up to an hour of exercise daily at least 5 days of the week while in the ICU. We have standard safety criteria to follow to start therapy and to stop therapy. It is possible that you may feel fatigued or short of breath during therapy. You can always ask to stop therapy.

Group 2: Regular Physical Therapy
You will receive physical therapy if and when your treating physicians determine you should receive it. You can always ask to stop therapy.

For Both Groups:
If you take part in this study, you will have the following tests and procedures: See Table.
All testing will be performed solely for this research study.
Please note that 2 phone calls will be required after discharge from the hospital— at 3 months and 6 months. During these phone calls we will ask you questions about your health and perform questionnaires designed to evaluate your health.

Other tests that we will have both groups undergo include:

1) Muscle Ultrasound: You will undergo an ultrasound to examine your muscles. This involves gel applied to your skin and then the ultrasound probe will be placed on the gel. It may warm the skin slightly. The specific regions that are examined with the ultrasound probe will be the leg. This will take no longer than 10 minutes.

2) Blood draw: 2 tubes of blood (about 2 teaspoons) will be withdrawn from a vein in your arm at each sampling time point for laboratory analysis of the blood cells and DNA.

3) Physical Function Testing: We will measure how fast you walk by asking you to walk at your normal pace for 15 to 20 yards (about 50 feet). You will do this test two times. We will measure how fast you can stand up from and sit down in a chair. We will test your balance by asking you to stand with your feet in different positions. We will measure muscle strength using a device that you grip and a device that you push against. These devices are FDA (Food and Drug Administration) approved devices, not experimental. We will also ask you how functional you think you are. To do this, you will watch a few short videos and answer questions about your ability to do the things demonstrated (such as walk up a flight of stairs). This will take <5 minutes.

4) Energy Analysis: We will measure your body's oxygen use and carbon dioxide creation. We will calculate the energy being used by your body. This will be done using non-invasive devices approved for this purpose. We will also use a device called an accelerometer to measure your movement throughout the day while you are in the hospital. This device is similar to devices like a pedometer or a simple Fitbit. You will be sent home with this device and asked to mail it back to us.

5) Healthcare Use Survey: We will ask you about your use of medical services since you were discharged from the hospital (for example, were you readmitted to the hospital).

6) Quality of Life Questionnaire: We will ask you how you feel about different aspects of your life (for example, your physical function or your social life). This will take <10 minutes.

7) Cognitive Testing: We will test your cognitive function with a simple test of memory, naming of objects, etc. This will take <10 minutes.

	Enrolment Day 0	Day 1	Day 3	Day 5	ICU Discharge	Hospital Discharge	3 months	6 months
Muscle Ultrasound	X		X	X	X	X		
Blood Draw	X	X	X	X	X	X		
Physical Function Testing	X				X	X		
Energy Analysis	X	X	X	X	X			
Healthcare Use Survey							X	X
Quality of Life Questionnaire						X	X	X
Cognitive Testing						X	X	X

Storage of Biological Tissue

If you agree to participate in this study, we will have approximately 2 teaspoons of blood withdrawn from a vein up to 6 times while in the hospital. These will be used for current and future research. The total amount of blood withdrawn during the study will be approximately 12 teaspoons. These samples will be kept and may be used in current and future research to learn more about other diseases. Your samples will be obtained during your stay at Wake Forest University Baptist Medical Center. The sample will be stored at Wake Forest Baptist Health and it will be given only to researchers approved by Rita Bakhru, MD. An Institutional Review Board (IRB) must approve any research study using your tissue sample. In order to participate in this study, you must be willing to provide this sample for future research.

Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be performed with your blood is not designed to help you specifically.

There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your blood will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

Your samples will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

How Long Will I Be in the Study?

You will be in the study for about 6 months after discharge from the hospital.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the therapy we are studying include:
Agitation: Rare
Pain (eg. at site of blood draw): Uncommon
Inadvertent Removal of a Tube/ Catheter (eg foley catheter, breathing tube): Rare
Low oxygen levels or difficulty interacting with ventilator: Uncommon
Low or high heart rate or blood pressure: Rare
Poor blood flow to heart muscle or abnormal heart rhythm: Rare
Risk of infection (related to blood draw): Rare
Risk of shortness of breath or fatigue during therapy: Possible
Irritation at the site of the activity monitor: Uncommon
You may experience discomfort, bruising and/or bleeding where the blood draw needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be: improved physical or mental function and improved quality of life.

Based on experience with physical therapy (both regular and with the in-bed cycler) in humans with acute respiratory failure requiring mechanical ventilation, researchers believe it may be of benefit to subjects with your condition. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have the options not to participate and to receive physical therapy if/when ordered by your physician team.
This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Neither you nor your insurance company will be billed for early physical therapy. However, you or your insurance company will be billed for regular physical therapy.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires

disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document (including research data in the medical record).

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a research study. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record.

WILL YOU BE PAID FOR PARTICIPATING?

You will be given $100 total in gift cards if you complete all the scheduled study testing. Upon return of the accelerometer (activity monitor) you will be provided a $50 gift card. Upon completion of each phone assessment, you will be provided another $25 gift card.

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be provided the gift cards.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Translational Science Center of Wake Forest University, the Pepper Center at Wake Forest University, the Critical Illness Injury and Recovery Research Center at Wake Forest, the Center for Diabetes, Obesity, and Metabolism at Wake Forest, the National Institutes of Health (the National Institute on Aging) and Ri, LLC. Ri is providing the in-bed cycler to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A

RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Rita Bakhru at [redacted] or (after hours) [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

Demographics: Age, Sex, Race, Height, Weight, etc
Hospital and ICU Information: Laboratory values, medications, procedures, PT, etc
Information about your discharge: medications prescribed, discharge location, etc
Information about your care after discharge: nursing visits, rehabilitation, etc

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least 6 years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Rita Bakhru that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Rita Bakhru
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research

study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. 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 Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A Wake Forest Baptist Medical Center (WFBMC) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because your condition worsened or it is in your best medical interest or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Rita Bakhru at [redacted] or (after hours) [redacted]

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm

CONSENT OF THE SUBJECT TO CONTINUE TO BE IN THE STUDY

Your legal representative gave his/her consent for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition has now improved. You are being asked to decide whether to continue to be in this study. Your decision is voluntary. This means your decision is up to you.

Subject Statement: I have read the information in this form. Or, someone has explained to me what study procedures will be continuing. My questions have been answered to my liking. I believe that I understand all of the information about this study. I have decided to continue taking part in this study.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm