UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM

Protocol Title:	Safety and Impact of Low Resistance Exercise Training On Quality of Life in Pulmonary Arterial Hypertension- **RESIST-PH**
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Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The purpose of the study is to learn more about how low-resistance training impacts frailty and the quality of life of people with pulmonary arterial hypertension (PAH). Low-resistance training is an evidence-based approach that may help patients improve their functional ability.

If you agree to join the study, you will be asked to identify caregivers to participate in the study with you. They do not have to live in your household. You will come in for a baseline in-person visit (week 1) where we will gather your demographic information, ask you about your medical history and medications, measure your height, weight, waist and hip circumference, take your vital signs, have you will fill out a questionnaires to assess your quality of life, test your physical performance, and show you the resistance training exercises to perform at your home. You will perform the exercises at home, as instructed, for 12 weeks. A research staff member will call you at weeks 4 and 8, to ask about how you are doing with the exercises. At week 12, you will return for a follow-up in-person visit, where we will measure your height, weight, waist and hip circumference, take your vital signs, have you will fill out a questionnaire to assess your quality of life, and test your physical performance. You and your caregiver will also be asked to

participate in an exit interview, where we will ask each of you, separately, how you felt about the resistance training.

You will be compensated up to $250 for completing all visits and the exit interview. If your caregiver participates in the exit interview, they will be compensated $50.

This study provides no direct benefit to you. Participating may help you experience better physical fitness and improved quality of life. Additionally, your participation could help us understand how low-resistance training helps patients with PAH, which can benefit you indirectly. The most common risks of participation are a breach of confidentiality, in which other people find out private information that you tell the study team, and experiencing physical distress while performing the exercises, which may include shortness of breath, dizziness, arm or leg cramps, and chest pain or palpitations. Our study team takes specific measures to maximize the benefits of the study and minimize the potential risks.

If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being asked to take part in a research study because you have PAH and have been on stable therapy for at least 3 months. You must also have the ability to access a telephone or videoconferencing call at 2 time points (for approximately 30 minutes) for 12 weeks.

Your participation is voluntary which means you can choose whether or not to participate. If you decide to participate or not to participate there will be no loss of benefits to which you are otherwise entitled. Before you make a decision, you will need to know the purpose of the study, the possible risks and benefits of being in the study, and what you will have to do if you decide to participate. The research team is going to talk with you about the study and give you this consent document to read. You do not have to make a decision now; you can take the consent document home and share it with friends and family.

If you do not understand what you are reading, do not sign it. Please ask the researcher to explain anything you do not understand, including any language contained in this form. If you decide to participate, you will be asked to sign this form and a copy of the form will be given to you so that you can find contact information and answers to questions about the study. You may ask to have this form read to you.

Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. You do not have to participate in any research study offered by your doctor. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study.

What is the purpose of the study?

The purpose of the study is to learn more about how a low-resistance training program impacts the frailty and quality of life in patients with PAH.

How long will I be in the study?

The study will take place over a period of 12 weeks, or about 3 months. This means that agreeing to participate in the study, you will complete a 12-week program of resistance training (intervention). At the 12-week mark, you will be asked to participate in an interview, which can be scheduled at your convenience. Your caregiver, if willing, will also be asked to participate in an interview.

What am I being asked to do?

The study consists of a 12-week at home low-resistance training program led by a trained member of the study team. This program is designed to increase your physical fitness and quality of life. During the active part of the study, you will perform exercise training sessions at home, as well as attend 2 in-person visits and 2 phone calls:

- Visit 1 – Baseline Visit (in person, 90-120 minutes):

  - Obtain your demographic information, review your medical history and medication list
  - Measure anthropometrics: height, weight, waist and hip circumference
  - Measure vital signs
  - Fill out a questionnaire to assess quality of life as it relates to your PAH
  - Complete a physical functioning test
  - A trained Physical Therapist will demonstrate and observe you perform the exercises
  - Dispense resistance bands, exercise diary, and exercise instructions

- Weeks 1 through 12 – Resistance Training (at home, 30-40 minutes per session):
  - You will perform the resistance training exercise sessions at home, 3 times a week for 12 weeks.
  - Each training session will consist of both arm and leg exercises, with 3 sets of 15-15-15 repetitions of each exercise. It is up to you how you schedule these 3 sessions throughout the week.
  - Log into the patient portal to complete your exercise diary after each session

- Visit 2 – Week 4 and Visit 3 – Week 8 (telemedicine video calls, 15--30 minutes each):
  - We will ask you if you are experiencing any physical symptoms related to the exercises (adverse events)
  - We will ask you about how the exercises are going for you, including watching you perform the exercises over the video call (if necessary)
  - Answer any questions you may have and troubleshoot any issues you are having
- Visit 4 – Week 12 (in person, 45-60 minutes):
  - Measure anthropometrics: height, weight, waist and hip circumference
  - Measure vital signs
  - Fill out a questionnaire to assess quality of life as it relates to your PAH
  - Complete a physical functioning test

- Exit Interview (phone or telemedicine video call, 45-60 minutes)
  - For both patients and their caregivers, there is an option to participate in a phone interview to talk about your experiences with the program. This interview will take place either by phone or video conference and will be audio recorded. We will conduct these interviews after the program has finished. This interview will take 45-60-40 minutes. You and your caregiver are eligible to participate in the interview even if you don't fully complete the 12 weeks of resistance exercise training. Additionally, patients and caregivers who choose not to take part in the study at all will also have the opportunity to participate in an interview to talk about why they made that decision.

What are the possible risks or discomforts?

There are minimal risks to the study. Performing an exercise program as a PAH patient may cause shortness of breath, dizziness, arm and/ or leg cramps, chest pain, or heart palpitations. If these were to happen, you would notify the research staff, and the exercise portion of the study would be stopped. You would be monitored and provided with medical care if necessary. To reduce these physical risks, at the baseline visit the exercises will be demonstrated for you, then you will perform them while being monitored by the study PI and a physical therapist. There is also the risk of a breach of confidentiality, in which other people find out private information that you tell the study team. To reduce the risk of this, all of the information you provide will be stored on secure computers or, in the case of written or recorded material, in a physically locked cabinet within a locked office. All information from the exit interview will be de-identified prior to transcription by a third party.

What are the possible benefits of the study?

There is no direct benefit to you. However, your participation could help us understand how resistance training exercises can help patients with PAH, which can benefit you indirectly.

What other choices do I have if I do not participate?

Your alternative to being in the study is to not be in the study. This will in no way impact or alter the care that you receive. You may choose to join the study or you may choose not to join the study. Your participation is voluntary.

There is no penalty if you choose not to join the research study. You will lose no benefits or advantages that are now coming to you, or would come to you in the future. Your doctor, nurse, or other health care professional will not be upset with your decision.

If you are currently receiving services and you choose not to volunteer in the research study, your services will continue.

Will I be paid for being in this study?

You may be paid up to $250 for completion of all study procedures. Payment will be divided up and given to you according to the following schedule:

- $100 for completion of the in-person Visit 1, Baseline Visit
- $100 for completion of the in-person Visit 4, Week 12
- $50 for completion of the optional exit interview

Participants are paid using a Greenphire Visa ClinCard, which is a rapid, secure payment method via a reloadable debit card that can be used at any accepting merchant or at any ATM or bank to withdraw cash.

Will I have to pay for anything?

There are no costs to you associated with participating in this study. The resistance bands are provided to you as a part of the study.

When is the study over? Can I leave the study before it ends?

The study is expected to end after all participants have completed all visits and all the information has been collected. The study may be stopped without your consent for the following reasons:

- The PI feels it is best for your safety and/or health-you will be informed of the reasons why
- You have not followed the study instructions
- The PI, the sponsor, or the Office of Regulatory Affairs at the University of Pennsylvania can also stop the study anytime

You have the right to drop out of the research study at any time during your participation. There is no penalty or loss of benefits to which you are otherwise entitled if you decide to do so. Withdrawal will not interfere with your future care. If you no longer wish to be in the research study, please contact Dr. Nadine Al-Naamani (Principal Investigator) at 215-615-4156 or nadine.al-naamani@pennmedicine.upenn.edu and inform us that you would like your study data removed from the study. There will be no consequences for withdrawing from the study. If you withdraw from the study, your data will be destroyed only if you request this. You may do this by contacting the Principal Investigator.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. Some examples are laws that require reporting of child or elder abuse and threats to harm yourself or others. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The Principal Investigator and staff involved with the study will keep your personal and medical information collected for the study strictly confidential. It will be kept in a secured file.

Will information about this study be available to the public?

A description of this clinical trial will be available on 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 website at any time.

What information about me may be collected, used, or shared with others?

Your data and responses, as well as the data and responses from other participants in this study, will be used to learn about how a low-resistance training program can help of patients with PAH.

For this study we will collect the following information:

- Name
- Personal characteristics such as date of birth, address, phone number, email address, gender identity, race, and level of education
- Medical record number
- Medical history

Study information about you will not be given to you or others (unless it is required by a government agency or other legal authority). This means that no one (not you, the caregiver who joins the study with you, your family, your doctor, your insurance company, or your employer) will have access to this information during the study.

Once your personal or medical information is shared with someone who is not a health care provider, it is not protected by the US federal privacy rules (called HIPAA). When you sign this consent form, you agree to have your personal and medical information used as described here.

If you choose to participate in the exit interview, we will record the audio and send the recording along with your study ID to a company that specializes in transcribing audio into written documents. This company follows strict rules to protect your personal information. After the audio is turned into a written document, any information mentioned in the interview that could be used to identify you, like your name or home address, will be taken out. Once the written document is ready, we will check it for accuracy and then delete the original audio recording. This written document will only be used to determine patients' and their caregivers' attitudes towards the resistance exercise training, which may help us design future exercise training programs for PAH patients.

Future Use of Data

Your information will be de-identified. De-identified means that all identifiers (such as name, date of birth, medical record number, date of hospitalization, address, etc.) have been removed. The information could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- Do the research
- Oversee the research

- See if the research was done right
- Evaluate and manage research functions

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

All study group members have undergone formal training in research standards prior to their participation in this study.

Who, outside of Penn Medicine, might receive my information?

- Those working under the direction of the investigator for the study (e.g., under subcontracts).
- All research centers participating in the study, even if they are not part of Penn Medicine.
- The funding Sponsor and organizations supporting the sponsor.

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)
- The study's Data and Safety Monitoring Board

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at 215-573-2540.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Printed Name of Participant	Signature of Participant	Date