

COVER LETTER

**Title: Cardio-pulmonary Rehabilitation and
Sleep Quality**

NCT Number: NCT04668599

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You are being asked to participate in a research study to learn about effects of cardiac and pulmonary rehabilitation (C-PR) on sleep quality. Participating in this study is voluntary. Your involvement will include completing a few questionnaires which will take about 40-45 minutes each time you complete the questionnaires. The questionnaires will include questions about your sleep, your daytime sleepiness symptoms, and your quality of life. We will request you to complete the same questionnaires at three different points, at the start and end of pulmonary rehabilitation, and after 3-months of completing the rehabilitation program. Also, we will want to collect information about the medical condition from your medical records – what type of disease it is, and how severe it is (based on lung function test, walking ability, blood test and imaging). This chart review will be for only data that already exists -we will not ask for or order additional testing. If you have already participated, let us know, as you cannot participate more than once.

This is a research study and participation is completely voluntary. Some of the questions you will be asked may make you feel uncomfortable. You have the right to skip any questions that you do not wish to answer or to stop your participation at any time.

Although this survey is de-identified, a rare risk of breach of confidentiality exists. Results will not be reported in any way that it would be possible to identify a participant.

The benefit to you for completing the study is if you are found to have high risk for sleep apnea or other sleep disorders, you will be notified so that you can tell your primary care provider and undergo testing and treatment for sleep apnea early. You will also be able to assess for yourself if you noticed any improvement in sleep quality after completing pulmonary rehabilitation and whether the beneficial effect of pulmonary rehabilitation lasts after 3-months of completing. This information will also be beneficial to the general population in terms of understanding additional benefits of pulmonary rehabilitation. You will also help researchers learn more about the effect of pulmonary rehabilitation on sleep quality.

Participants will receive a gift card of \$20 total, which will be given at the end of the study:

- \$10 for completion of questionnaires/surveys at baseline after completion of C-PR
- \$10 for completion of questionnaires/surveys at baseline 3 months after completion of C-PR

If you withdraw from the study, you will be paid for the portions of the study that you have completed. A \$10 gift card will be given to you in person or mailed to your address on file at the end of pulmonary rehabilitation after return of completed questionnaires. Another \$10 dollar gift card will be mailed to your address on file after return of completed questionnaires 3- months post-rehabilitation.

A decision to not participate in this study will not affect your medical care or result in any loss of benefits to which you are otherwise entitled. If you are an employee or student, your decision to participate or not will not impact your employment or student standing.

If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints, please contact the MetroHealth Medical Center's Institutional Review Board (which is a group of people who review the research to protect your rights) at 216-778-2021.

By completing this questionnaire, you are agreeing to participate in the study. If you do not wish to participate in the study, then simply do not complete the questionnaire. When you are done with the survey, please send it back to MetroHealth either through MyChart if you are a MyChart user or bring the filled questionnaires with you on the day you are scheduled to start pulmonary rehabilitation. For follow up surveys at the end of C-PR and 3-months post completion of rehabilitation, the completed surveys can be returned either through MyChart if you are a MyChart user or mailed back using the stamped return envelope which will be sent to you.