# PARTICIPANT INFORMATION SHEET AND CONSENT FORM

# for Participation in a Scientific/Clinical Study\*

Participant's Full Name	
Age	
Phone Number	
Email Address	

### **Study Title:**

Research project within the framework of independent research: Evaluation of the effects of physiotherapy in patients with Chronic Obstructive Pulmonary Disease (COPD).

### **Study Objective:**

To evaluate the effects of physiotherapy in patients with Chronic Obstructive Pulmonary Disease (COPD).

#### **Study Duration:**

From June 1, 2023 to January 15, 2024.

#### **Brief overview of the study procedure:**

All patients will be qualified for a pulmonary rehabilitation program that will include cycle ergometer training, cardio-respiratory and general fitness exercises, inhalation therapy, postural drainage and effective coughing techniques, as well as chest percussion.

The core component will be cycle ergometer training – once or twice daily, 6 days per week; 30-minute group cardio-respiratory and general fitness exercises in the gym – once or twice daily, 6 days per week; inhalation therapy – once daily, 6 days per week; postural drainage and effective coughing – once daily, 6 days per week; chest percussion – once daily, 6 days per week.

The rehabilitation program will comply with ATS and GOLD standards.

#### Method of Measurements or Data Collection:

To qualify COPD patients for physiotherapy, the following assessments will be conducted: exercise tolerance (6-minute walk test - 6MWT), dyspnea (10-point Borg scale), degree of pulmonary function impairment (FEV1), and physical performance (Timed Up and Go test - TUG). These assessments will allow the physiotherapy program to be tailored to the individual capacities of each patient.

Exercise tolerance will be assessed using the 6MWT. Based on the walking distance and time, walking speed and energy expenditure will be calculated, expressed in METs (Metabolic Equivalent of Task).

The spirometric parameter used to determine qualification for physiotherapy will be the forced expiratory volume in one second (FEV1).

Physical performance will be assessed using the Timed Up and Go (TUG) test. The purpose of this test is to evaluate agility and dynamic balance. The time needed to complete the task will serve as the test result.

#### **Potential Risks:**

None.

# **Right to Withdraw:**

Participants may withdraw from the study at any time without any consequences.

## **Data Privacy:**

All data will be anonymized and coded. Personal information will be protected and used exclusively for scientific purposes.

#### **Additional Health Insurance:**

Not required.

### **Participant Declaration:**

- I confirm that I have received detailed information about the study, including its benefits and risks.
- I understand that I may ask questions and receive clear answers.
- I am aware that I may withdraw at any stage.
- I understand that additional health insurance is not necessary.

#### **Voluntary Participation Consent:**

I agree to take part in this study: YES / NO\*

I consent to the processing of my personal data, including archival and statistical data, by PWSZ in Nysa, in accordance with Article 23(1)(1) of the Personal Data Protection Act of August 29, 1997 (Journal of Laws 2002, No. 101, item 926, as amended): YES / NO\*

Date, Participant's Signature	Date, Principal Investigator's Signature
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<sup>\*</sup> Delete as appropriate