Study Subject Consent Form

Consent Form Version:	Version Ver.1.0					
Study Title	Importance of proper ventilator support and pulmonary rehabilitation in obese patients with heart failure: A case series					
Research Director	Affiliation	[redacted]	Name	[redacted]	Contact	[redacted]
Research Representative	Affiliation	[redacted]	Name	[redacted]	Contact	[redacted]
24-Hour Researcher Contact Information			Name	[redacted]	Contact	[redacted]

*** If you have any questions about this study, or if you experience any risk, inconvenience, or injury, please contact the research director or the research representative.**

1. Invitation to participate in the study

You have been invited to participate in this clinical trial. The research director will comply with the relevant regulations when obtaining consent from you to participate in the clinical trial and documenting the data, and will follow lawful procedures considering the ethical principles based on the Declaration of Helsinki.

Please read this consent form carefully before deciding whether or not to participate in this clinical trial. It is important that you understand why this research is being conducted and what it entails. You are welcome to ask any questions as you read this document. Please give yourself plenty of time to understand this process and feel free to ask as many questions as you need to in order to decide whether or not to participate in this study.

When all your questions have been answered and you have decided that you would like to participate in this study, please sign this document to begin your participation. You and the research director (or a delegate authorized by the research director) must sign and date this form by hand. Your signature means that you have been informed about the study and its

risks. In addition, your signature on this document means that you (or your guardian) wish to participate in this study.

2. This clinical trial will be conducted for research purposes

3. Background and purpose of the study

The purpose of this study is to describe two HF patients in whom symptoms improved after arterial blood gas (ABG) levels were normalized with the aid of non-invasive ventilation (NIV) without intubation, which was administered after medication and oxygen supply treatment proved ineffective due to severe hypercapnia.

4. Information on drugs (or medical devices/procedures, etc.) used in the clinical trial and the probability of being randomly assigned to the test or control group

This study does not involve a randomization process because it is of a case report format and will be performed as a retrospective medical record review.

5. Tests or procedures to be performed on the study subjects in the clinical trial, including invasive procedures

This study will be conducted on cerebral palsy patients who have already undergone electromyography (TMS-EMG) and imaging (MRI/DTI) investigations. A retrospective medical record review will be performed; therefore, no additional investigations will be required. You need not comply with any study-related requirements. There will be no changes in your treatment regimen or overall health if you agree to participate in this study.

6. Expected benefits to the study subjects from participation

Participation in this study does not involve any risk or inconvenience and does not entail any unexpected risks. You will not benefit directly (no therapeutic benefit) by agreeing to participate in this study.

7. Compensation or treatment to be given to the subjects in case of clinical trial-related issues

This study is a retrospective medical record review, which will not cause any harm to the study subjects.

8. Financial reward or cost for participation

Monetary compensation will not be provided and you will not incur any additional costs for participating in this study.

9. Voluntary consent, participation withdrawal, and reasons for withdrawal

Your participation in this study is voluntary and you will not be penalized if you do not agree to participate. Even if you agree to participate, you can withdraw your consent at any time. By signing this form, you are indicating that you are participating voluntarily and you can withdraw from the trial at any time. Your treatment at this hospital will not be affected and you will not be discriminated.

If you withdraw your consent to participate or if your participation is stopped for any other reason

- Information collected during your participation may be archived and included in the final results of the clinical trial. No personally identifiable information will be included in the results.
- No new data will be collected.
- Personal information will not be used for any purpose other than the contents agreed by the provider, and if you wish to refuse the use of the provided personal information, you can request to view, correct, or delete it through the person in charge (research director).

The investigator may inform your primary care physician that you are participating in a clinical trial and may request medical information about you.

10. Confidentiality and protection of privacy

Records that identify you are confidential and not publicly available. However, within the scope permitted by the relevant laws and regulations, to verify the reliability of the clinical trial procedure and data, the monitoring personnel, inspector, review committee, and

government agencies may directly view your medical records or data. However, even in this case, we will try to keep the information as confidential as possible. By signing this consent form, you permit direct access to these materials, and your identity will be kept confidential when the research results are published.

11. Purpose, use, and storage period of personal information

Your personal information collected during the research will include height, weight, birth history, drug treatment history, imaging results, outpatient records, and hospitalization records. The recorded information will be strictly managed in accordance with the relevant laws and regulations, and only the person in charge of the research can access the same. Personally identifiable information is not used or required for the study directly, and is used only to link you with the specimens and clinical data. Your personal information will be used and stored for up to 3 years from the completion of the research. During this period, the information will be properly managed in accordance with the Personal Information Protection Act and will be disposed subsequently.

12. Regarding new information that may affect the subject's willingness to continue participation

We will notify you or your guardian in a timely manner as new information becomes available that may affect your willingness to continue to participate in this study.

13. Study subject consent

- ✓ I have been explained about the contents of this consent form in detail and have discussed the same with a study-affiliated doctor/researcher.
- ✓ I have read and understood the terms of the consent form and have had the opportunity to ask questions and received satisfactory answers to all of my questions.
- ✓ I agree to participate in this clinical trial on a voluntary basis. signing this agreement does not waive my rights.
- ✓ I am free to withdraw my consent at any time and I understand that this will not affect my care or my rights.
- ✓ I understand that I will be provided with a signed and dated copy of the consent form.

Study Subject

Name: [redacted] **Signature:** [redacted] **Date:** [redacted]

Guardian **Name:** **Signature:**

(If required)

Relationship to Subject **Relationship:** **Date:**

Research Director or Delegate

Name: [redacted] **Signature:** [redacted] **Date:** [redacted]