## Subject Information and Consent

Respiratory and Critical Care Medicine Team

Pamela Youde Nethersole Eastern Hospital

**Evaluation of the effect of continuous positive airway pressure treatment on cardiopulmonary exercise response in Chinese patients with moderate to severe obstructive sleep apnea**

***Study background and purpose***

Obstructive sleep apnea (OSA) syndrome is a common respiratory disease. Current evidence showed that in OSA patients, repeated apnea episodes leads to impaired cardiopulmonary function and increased risk of cardiovascular diseases. Continuous positive airway pressure (CPAP) treatment is one of the effective OSA treatments. This study aims to prospectively evaluate the effect of continuous positive airway pressure treatment on exercise response in Chinese patients with moderate to severe obstructive sleep apnea syndrome. We hope this study will be able to provide data about the relationship between OSA treatment and cardiopulmonary function. This is a single-center study involving Pamela Youde Nethersole Eastern Hospital.

***Study details***

This study takes three to six months to complete and it aims to recruit 60 volunteers. The targeted populations are the OSA patients diagnosed by polysomnography in our sleep laboratory. If you agree to participate in this study, we will arrange the following for you:

1. Chest X ray, electrocardiogram, blood test, cardiopulmonary exercise test, sleep questionnaire and CPAP titration with optimal pressure prescription will be arranged by our respiratory specialists.
2. Echocardiogram with be performed by our cardiologists.
3. Diet habit assessment and advice will be offered by our registered dietitian
4. Follow up appointment will be arranged after the aforementioned investigations and the results will be explained by our respiratory specialists
5. Second cardiopulmonary exercise test will be arranged after three months of CPAP treatment.
6. Your medical record will be documented by our investigators.

All of the study results are kept confidential. Hong Kong East Cluster Research Ethics Committee has the right to access the subject’s records if needed.

***Any potential side effects in participating in this study?***

 This study does not involve new medication or treatment procedure. All the aforementioned investigations are proved to be safe in previous international studies. Personal data collected during the study will be stored for at least 5 years. Records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Your personal identification will be hidden in all statistical analyses and data reporting.

***Confidentiality***

Your medical record cannot be accessed by any parties except your doctor-in-charge, Ethics Committee staffs and investigators of this study. Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance (Cap. 486), you shall have the right for the protection of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his office (Tel No. 2827-2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorize:

* the principal investigator, the research team and Research Ethics Committee (Hong Kong East Cluster) of Hospital Authority are responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
* the relevant government agencies (e.g. the Hong Kong Department of Health, Hospital Authority) to get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

***Do I have to participate in the study?***

Being in this study is completely voluntary, and if you do participate, you can withdraw from it at any stage if you want to. It will not influence your treatment or your relationship with your doctor or any other hospital staff if you do this. If you decided to withdraw from the study, we will continue to handle the data we collected before your withdrawal unless we received your request to discard all your study-related information on this study. Subjects will have enough time for considering the participation in this study. If you have any queries about the study, you can contact our investigators (**Dr Cheng Hei Shun and Dr Chiu Pui Hing**) or the Hong Kong East Cluster Research Ethics Committee at 2595- 6111.

New Information

If any new information about the research study becomes available which may influence your decision to continue in the study, you will be told in a timely manner. During the study, you will be notified of changes to study procedures, newly discovered side effects or significant findings which may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this study.

Participant Consent Form

I have read and understood the Subject Information and Consent on the above named research study. I have collected sufficient information regarding this study.

If I have any physical or emotional discomfort as a result of participating in this study, the study investigators will treat me, or will refer me to receive treatment. Signing this informed consent form does not imply that my legal rights would be waived.

I also understand that the research study is strictly confidential.

I understand my identity will be kept confidential. I also authorize the research ethics committee and the regulatory authority(ies) to access my data for verification of clinical trial procedures and/or data, without violating my confidentiality, to the extent permitted by the applicable laws and regulations.

I freely choose to participate in this study and I understand I can withdraw at any time.

I hereby agree to participate in this research study.

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Name of Participant Signature Date

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Name of Impartial Witness Signature Date

(if applicable)

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Name of Investigator Signature Date

By signing a written informed consent form, I will be given a signed and dated copy of the consent form and information sheet for storage