

TUNG WAH COLLEGE
Informed Consent Form for Adult

“Comparison of new and conventional N95 fit testing protocols for three respirators with different designs: Evaluation of equivalence and reproducibility”

You are invited to participate in a research study conducted by Professor Simon C. Lam in the School of Nursing at Tung Wah College (TWC).

PURPOSE OF THE STUDY

This study aims to investigate the equivalence of fit testing results (i.e., pass or fail) as well as the reproducibility of fit testing results (specifically the fit factor) of three different designed respirators tested among Chinese HCWs using the new and conventional protocols.

PROCEDURES

The participant will perform the routine fit testing only with three different types of N95 respirators.

Please be assured that you have right to decide whether to participate or not. You can also withdraw from this study at any time during the process. All your personal data will be used for research purpose and it will be kept strictly confidential and anonymity.

POTENTIAL RISKS / DISCOMFORTS AND THEIR MINIMIZATION

Wearing the N95 respirators may cause some minor discomforts like feeling hot and stuffy, tightening of face, interference on speaking, skin itchiness, mask displacement, discomfort on ear lobe, interference on working efficiency, and mist over glasses. In Phase 2 CPR session, a few people will pant or experience other minor discomforts due to vigorous movement.

To ensure your safety in both phases, our team of researchers will continuously monitor your conditions. If you have any problems at any time during the study, you can approach our researchers for help. Adequate rest time will be given between different procedures to minimize discomforts.

COMPENSATION FOR PARTICIPATION

To thank for your participation, \$200 cash coupon will be given as a token of appreciation upon completion. For those repeated fit testing, \$300 cash coupon will be given upon completion.

POTENTIAL BENEFITS

Wearing a well-fitting N95 mask in handling patients with infectious respiratory diseases is a life-saving procedure. We will provide you training on proper donning and doffing of N95 masks. If fit test of designated mask is requested by your institution of work or study, you will obtain all the full reports of fit tests right after the procedures.

The collected data is of substantial value in the research field of prevention and control of

infectious disease.

CONFIDENTIALITY

Strict confidentiality is promised and that the information obtained in the study will be used for research purposes only. Research data is kept in secure and safe place. You have the right to review and erase the records by anytime.

Responsible members of TWC may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

DATA RETENTION

Data would be kept in a secured and accessible form in the campus of Tung Wah College for at least seven years after publication or public release of research work. Personal identifiers will be removed upon the completion of study / stored separately for long term retention of the research data.

PARTICIPATION AND WITHDRAWAL

If your institution requests the fit test result of a designated N95 respirator, your withdrawal of that fit test may affect your job or study arrangement. After the designated mask fit test, your participation is voluntary. This means that you can choose to stop at any time without negative consequences.

QUESTIONS AND CONCERNS

If you have any questions or concerns about the research, please feel free to contact Professor Simon Lam Ching at TWC, Room 1601H, School of Nursing, Ma Kam Chan Memorial Building, Tung Wah College, 31 Wylie Road, Homantin, Kowloon, Hong Kong. Tel: 3468 6854. Email: simonlam@twc.edu.hk if you have any enquiries.

If you have questions about your rights as a research subject, contact the Secretary, Research Ethics Committee (REC), TWC (ro@twc.edu.hk).

SIGNATURE

I _____ (Name of Subject)

understand the procedures described above and agree to participate in this study.

I ** wish / do not wish to be identified. (if the procedure will involve personal interview)

(** Please delete as appropriate.)

Signature: _____

Date: _____