An Epidemiological Investigation on Correct Wearing of Mask by Hood Test

Informed Consent Document

Program No：2020-KZLXB-02-02

Version Date：June 18, 2020

Version No:　version 3.0

Research Unit（Seal）：Fuwai Yunnan Cardiovascular Hospital

Research time: June 2020 to August 2020

Information and informed consent forms of subjects participating in the survey

Research title: An Epidemiological Investigation on Correct Wearing of Mask by Hood Test.

Program number: 2020-KZLXB-02-02

Sponsor: Fuwai Yunnan Cardiovascular Hospital

Organization name： Fuwai Yunnan Cardiovascular Hospital

Address： No. 528 Shahe North Road, Wuhua District, Kunming City, Yunnan Province

Telephone： 0871-68285636

Part 1 Instructions for participants

You are invited to participate in an epidemic investigation of correctly wearing a mask to prevent respiratory infectious diseases in Fuwai Yunnan Cardiovascular Hospital, referred to as Yunfu (Address: No.528 Shahe North Road, Wuhua District, Kunming City, Yunnan Province. Telephone: 0871-68285635). Before you decide whether to participate in this study, please read the following carefully, which will help you understand why we are conducting this epidemic survey, including describing the benefits, risks and discomfort you may gain if you decide to participate. It also describes that you have the right to withdraw from the experiment at any time. If you have anything you don't understand during the reading process or would like to know more about it, please feel free to contact your research doctor or staff. The research doctor will answer any questions you may have about the trial or this informed consent document. Participation in this survey is entirely voluntary.

1. What is the purpose of this clinical trial?

As the effect of correctly wearing masks to prevent respiratory infectious diseases is not fully understood, this study will conduct a group of investigations on how to correctly wear masks to prevent respiratory infectious diseases. By testing whether you can feel the taste of the test potion, to determine the correctness of the mask you are

wearing, and to fully understand the effect of wearing the mask correctly.

The experimental design has been reviewed and approved by the Ethics Committee.

2. Who should take this test?

People aged 7 and above and in good health will be invited to participate in this survey. If you are pregnant, plan to become pregnant or breastfeed during the trial; if you have a respiratory disease or smell strain within nearly a month, you should not participate in this trial.

3. What will happen if I take the test?

The research doctor will first collect the subjects' age, sex and education level, then observe the type of mask they wear and ask them to take a deep breath to see if the mask is close to their face. The research doctor then sprayed the subjects with ordinary saline with taste and asked them if they felt the smell. Those who feel the taste will issue qualified disposable medical masks, demonstrate the correct way to wear the mask, and spray ordinary salt water with flavor again, the whole process takes about 5 minutes. After the test, it will be treated as medical waste and the reagent container will be disinfected.

4. What is your responsibility in the trial?

If you participate in this experiment, you will follow the following points:

- Follow the requirements of the research doctor.
- Agree to participate in the testing activities, these procedures are part of this experiment.
- Inform your medical staff in time whether you feel the smell of the reagent.
- If you want to quit the trial, please inform your medical staff.
- No smoking is allowed during this trial.

5. What are the possible risks, side effects or discomfort associated with participating in this trial?

The reagent is based on normal saline and is made by adding ordinary liquid with flavor. it has been used in clinical test for a long time and the result is safe. It will not cause irritation or injury to the body or skin, nor will it cause chronic poisoning and other health hazards.

May cause mild discomfort due to the taste of the reagent: such as headache, dizziness, nausea, facial skin discomfort and other symptoms. If it happens, you can inform the medical staff in time.

6. What are the possible benefits of participating in this trial?

The trial is conducted among healthy volunteers, which meant that all participants are in good health, not because of the study of masks for the treatment of respiratory infections. Therefore, although you will perform some tests that will provide information about your health, you will not benefit from participating in this trial.

The information obtained from this test will improve your ability to wear a mask correctly and increase your awareness of the prevention of respiratory diseases. The test results will help medical staff to improve the publicity and education of wearing masks and health promotion policies, which will help the whole society to prevent respiratory infectious diseases.

7. Voluntary participation or withdrawal

Your decision to take this test should be entirely voluntary. You may withdraw from this test at any time for any reason and will not adversely affect you (and your child).

8. Protection of the rights and interests of minors and children with amblyopia

If you are a subject under the age of 18 (excluding 18 years old) to take part in this test, the school will seek the consent of the legal guardian (parents) on behalf of the school, and the medical staff can also demonstrate the test process by video. Let minors know and fully understand, if you agree to the test, you need to sign and agree to participate in the test.

9. Will my participation in this experiment be kept secret?

This test will not collect any privacy-related information about you, will not involve the disclosure of your personally identifiable information (for example, name or address), and will not infringe upon your privacy. Your medical data and records of your participation in this trial will be submitted to the research party and stored in a secure repository to control the data. Some of your personal data collected during the test may be transmitted to Fuwai Hospital of the Chinese Academy of Medical Sciences, located at 167 Beilishi Road, Xicheng District, Beijing.

The results will be used for experimental reports, article publication and policy research.

10. Emergency contact information or Ethics Committee contact information

During the test, if you encounter any medical problems, or suffer from research-related injuries, or have any questions, doubts or dissatisfaction about this test, please contact Dr. Pan Xiangbin, Fuwai Yunnan Cardiovascular Hospital, Tel: 010-88396666).

With regard to this test, if you have any questions, doubts or dissatisfaction about the test unit and test method, you should write to the Ethics Committee: (contact: Mr. Yang, Tel: 0871-68521251).