Informed Consent	
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The cohort study for chronic obstructive pulmonary diseases (COPD) in China----- Observation of the disease outcome and identification of prognostic biomarkers for the disease outcome

Principal Investigator: Chen Wang/Kewu Huang

Informed Consent

Subject initials _____

Code _____

You have been invited to participate in National Key Research and Development Program of China "The cohort study for chronic obstructive pulmonary diseases (COPD) in China --- Identification of prognostic biomarkers for the disease outcome" (No: 2016YFC0901102). Please read this informed consent carefully and make the decision carefully whether to participate in this study. Your participation is completely voluntary. You must show the signed consent before participating in clinical studies. You can ask about what you do not understand when the doctor or investigator discusses the informed consent with you. We encourage you to talk with your families and friends before making the decision. You have the right to refuse, or withdraw from the study at any time, which is of no punishment or loss of your rights. Please tell your investigating doctor or investigators if you are participating in other studies. The study background, objective, process and other important information are as follows.

1. Background

Chronic Obstructive Pulmonary Disease (COPD), a common preventable and treatable disease, is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways. The overall prevalence of COPD was 8.2%(men, 12.4%; women, 5.1%) (40 y) in China. It seems the prevalence is still growing concerning the high smoking rate, increasing aging population and serious air pollution in China. Recently, some big cohort studies about COPD have been conducted in the world, and some specific phenotypes and valuable biomarker have been identified in COPD patients. However, currently there is few COPD studies to describe the biomarkers of the COPD patients longitudinally and few biological databases established in China.

2. Objective

The study is to observe the disease outcome and identify prognostic biomarkers for the disease outcome.

3. Process

3.1 How many patients will participate in this study?

Approximately 11,800 people will participate in this study and about 3,800 among them will be invited to attend a more than five-year follow-up.

3.2 Steps

If you agree to participate in this study, please sign this informed consent.

Before recruited in the study, your doctor will ask about your medical history and then record it, and you will have pulmonary function test, chest imaging screening test.

You will then have baseline visit if you are recruited.

During the baseline visit, the doctor will ask about your basic information, smoking history, occupation, medical history, respiratory symptoms, treatment, etc. You will also be required to complete questionnaires regarding your disease and the quality of everyday life. You will have pulmonary function test (including spirometry, lung volume measurement, diffusion function), chest CT, 6-minute walk test and 10 ml of blood will be collected from your arm vessels with a needle. Within a week after the baseline visit, we will record your daily activities.

You may be invited to attend a follow-up, and you will be asked to come to hospital once a year for five years after your baseline visit so that we can better understand your conditions.

Your doctor will ask you about your conditions, smoking history, respiratory symptoms, treatment, etc. You will also be required to complete questionnaires regarding your disease and the quality of everyday life. You will have pulmonary function test, chest CT or chest X-ray, 6-minute walk test, and 10 ml of blood will be collected from your arm vessels with a needle. Within a week after each visit, we will record your daily activities.

The doctor will call you every 3 months to ask about the changes of your conditions.

All your treatment is completely decided by your physicians. There is no additional medication during the study.

There will be 6 blood collections and 10 ml for each time, 60 ml in total.

3.3 How long will the study last?

There will be a telephone call every 3 months during the study, and you will be asked to come to hospital once a year for more than five years after your baseline visit so that we can better understand your conditions.

You can withdraw from the study at any time without losing your benefits. However, we encourage you to discuss it with your doctor before you quit.

If you have a serious adverse event, or if your investigating doctor feels it inconsistent with your best interests, he / she will let you drop out. Sponsors or regulators may also halt the study. Your withdrawal will not affect your medical care

and rights.

If you withdraw from the study for some reason, you may be asked about your participation. You may have laboratory tests and physical examination if the doctor considers it necessary.

3.4 The Information and Biological Samples

Blood sample will be collected at sites and transported to central lab to test for biomarkers, which will then be preserved in central lab and tested in the future for inflammatory mediators, proteomics, genetic testing, etc. An electronic data capture (EDC) system will be used in this study. A password-protected web-based data entry platform was used to enter data of each site. The questionnaires and other relevant information about your diagnosis and treatment will be preserved in strict confidentiality to ensure that your information will not be disclosed. The information collected will only be used for purpose of this research.

4. Risks and Benefits

4.1 What are the risks involved in this study?

The risks associated with attending this study may be as follows. You should discuss these risks as follows with your investigating doctor, or your regular physician if you like.

During this observational study, you may experience some, all, or none of these adverse events, risks, discomforts, inconvenience, such as discomfort of venipuncture for blood sample collection, and infection risks. We will try to avoid the infection and guide you how to prevent being infected.

6-minute walk test may bring discomforts. Complete the test based on your strength, the doctor will accompany you to complete and assess the safety. There may be information security risks. We will do our best to protect your information from being disclosed. Some questions we ask may make you feel uncomfortable, which you can refuse to answer. You can withdraw from this study at any time.

You will be asked to come to hospital regularly and have some tests, which will take some time and may cause inconvenience.

4.2 What are the Benefits?

Direct benefits: You and your physicians will learn more about your conditions and you will have better management of disease with the help of the investigating doctor.

Potential Benefits: We will pay sustained attention to the changes of your disease which may be helpful to slow the progression. Conclusions will be reached from this study that could benefit you and those who are in the same conditions.

5. Alternative treatment

There is no alternative treatment in such an observational study.

6. The Use of Research Results and the Confidentiality

Results of the research may be published in medical journals, with the understanding and assistance of you and other participants, but confidentiality of your personal and health information will be preserved. Personal information will be preserved in strict confidentiality, and will not be disclosed unless required by law. Government agencies, hospital ethics committees and other relevant investigators may have access to your medical records when necessary.

7. Study costs and compensation

7.1 Study drugs / equipment and related testing costs

The data collected in this study is partly from the necessary tests in the usual clinical visits, the costs of which will not be compensated for. Other tests that cannot be covered in usual clinical visits will be free. The routine treatment and tests for the complications will however not be free.

7.2 Compensation

After participate in this study, we will give you a certain degree of financial subsidies, 5 follow-up after the baseline visit,

You will receive financial compensation (including transportation) for participating in this study. There will be 50 yuan for each visit after the baseline visit, the amount of which is in accordance with the actual completion.

There will be no provisions to compensate study participants for you will not be required to attend additional visits or take additional drugs but will follow the usual clinical practice.

However, compensation may be considered if the research institution fails to perform in accordance with established study protocal, causing damage to the subject due to the medical mistake. Research institutions will bear the medical expenses for subject, and take the corresponding compensation / or responsibility to compensate.

8. Rights and Considerations

8.1 Rights

Your participation is completely voluntary. Your medical care will not be affected if you decide against to participate in this study.

If you decide to participate you must sign the consent form. You are entitled to withdraw from the study at any time without discrimination or unfair treatment, and your medical care and benefits will not be affected.

8.2 Considerations

As a subject, you need to provide a true picture of your medical history and your current physical conditions. You need to tell your investigating doctor about any

discomfort, and stop some certain medicines to have some tests before your visit under the guidance of your doctor. Let your doctor know if you have recently participated in other studies or are currently participating in other studies.

9. Contact information

Your doctor will inform you promptly of any important new information that may affect your willingness to continue to participate in the study. You are entitled to know which personal data has been collected, or the conclusions of the study. You can raise any questions about this study at any time, all of which will be answered. Please contact_____by telephone No:_____.

This study has been approved by the Ethics Committee. If you have any questions about your rights / benefits or if you want to reflect any difficulties, complaints, or concerns you may have about your participation, or if you would like to give comments and suggestions about the study, please contact the Ethics Committee, Contact telephone No:_____, E-mail:_____.

Subject Signature Page

Informed Consent Statement:

I have been informed of the objective, background, process, risks and benefits of the study. I have been provided time and opportunity to ask questions, the answers of which are satisfing.

I have also been told whom to contact when I have a problem, want to reflect difficulties, concerns, suggestions, get more information, or offer help.

I have read this informed consent and I agree to participate in this study.

I have known I can choose not to participate in this study or withdraw from this study at any time without having to provide an explanation.

I have already known that if I were in a worse condition, or if I had a serious adverse event, or if my investigating doctor thought it is inconsistent with my best interests, he/she will decide to let me withdraw. Sponsors or regulators may also halt the study without my consent, of which I will be inform in time and other options will also be given through discussion with my investigating doctor.

I will receive a copy of this document, which contains the signature of myself and the investigator.

Signature of Subject：_____ Date：_____

（PS: if the subject is incapacitated / restricted in capacity, the signature of legal acceptable representative and signature date are required）

Contact of Subject：_____

Signature of Subject's Legal Acceptable Representative：_____ Date：_____

（PS: If the subject cannot read the informed consent, an independent witness is required to prove that the subject has been informed of all the informed consent. Signature of the independent witness and signature date are required）

Contact of Subject's Legal Acceptable Representative：_____

Signature of Independent witness：_____Date：_____

Contact of Independent witness：_____

Signature of investigator：_____ Date：_____

Contact of investigator：_____