Project Title :_____ Biomarker Discovery in Lung Cancer-Malaysia_____

Protocol ID :_____PRO-MAS-002_____

Sponsor : _____MiRXES Pte Ltd_____

Investigator : _____ Associate Professor Dr. Poh Mau Ern _____

You are being invited to participate voluntarily in the study entitled: **Biomarker Discovery in Lung Cancer-Malaysia** under the supervision of **Associate Professor Dr. Poh Mau Ern.**

Before you agree to join in the study, you need to know the risks and benefits so you can make an informed decision. This process is known as **informed consent**.

This consent form tells you about the study that you may wish to join. Please read the information carefully and discuss it with your relatives or friends. If you have questions, please ask the Study Doctor to answer them.

PURPOSE AND CONDUCT OF THE STUDY

This study aims to

a. Identify biomarkers and signatures to differentiate between high-risk and lung cancer patients.

b. Discover blood-based biomarkers that can be used as an adjunct test to imaging diagnosis to improve patient follow-up.

In this study you will **not be receiving any interventions as this is an observational study.**

Your responsibilities as a study subject includes following the directions instructed by the Study Doctor. The study will include the following steps:

a. You are invited to participate in this research study because you underwent an imaging diagnosis (X-Ray or Low-dose CT) for the investigation of Lung Cancer as per standard of care. If you are deemed suitable for the study, you will be classified into 1 of 2 cohorts based on your imaging result:

   (i) Cohort A; Non-cancer cohort. If you were diagnosed with a condition that has a high risk of progressing to Lung Cancer, you will be classified under Cohort A
   (ii) Cohort B: Cancer Cohort. If you have been diagnosed with Lung cancer based on your imaging results, you will be classified under Cohort B.

b. The study team will discuss with you on the Patient Information Sheet (PIS) and the Informed Consent Form (ICF) for this study. This will need to be completed with the your understanding of the risk and benefits of this study. Upon completion of the ICF, the doctor may review your medical history to determine your suitability for the study.

c. You will be asked about your demographics, lifestyle, personal health data, family history of diseases, past medical history and other clinical management data. Study team will collect this data.

d. During this study, you will undergo blood sample collection at 2 different time points. Blood collected will be up to 39 ml or 8 teaspoons per time point. The study blood collection will occur during your standard of care visits.

e. A tissue biopsy collection may be performed as part of your standard of care with the hospital.

f. Your medical records will be reviewed for data collection for research purposes.

The Study Doctor may remove you from this study for any justified reason according to the protocol. Examples why you may have to stop some or all study-related activities, are:

1. Staying in the study would be harmful to you.
2. You need treatment that is not allowed in this study.
3. You fail to follow instructions.
4. The study is cancelled.
5. Blood sample provided was not sufficient for the purposes of the study.

RISKS AND INCONVENIENCES

The risks you may encounter by participating in the study it is unlikely to result in possible side effects of the study medicine or of those related to the study procedures as this is an observational study.

While the collection of blood and/or tissue samples are generally safe, you might experience some mild side-effects. For blood withdrawal, you may experience dizziness which should not last more than a few hours and/or bruising at the collection site which typically may last up to two days. In case adverse events occur due to the collection of blood, you will be referred to and managed by a physician. Sponsor maintains insurance coverage for this study. The sponsor will reimburse the you, through the insurance provider, for the reasonable and necessary cost of complications for the study related injury (in particular to blood collection) and provide appropriate compensation based on the guidelines of the insurance policy.

Problems or side effects that are not currently known is also unlikely to occur. Be assured that you will be provided with new information that may affect your willingness to start or continue in the study.

BENEFITS

You will not directly benefit from this research. However, donating your samples for research purposes will allow us to determine whether blood may predict the severity of the cancer, and/or understand the incidence of genetic mutations of lung cancer in a Malaysia.

The data generated will contribute to the understanding and improvement in cancer diagnosis and treatment.

FINANCIAL CONSIDERATIONS

You will not be charged any additional fees and payments for the research work that will be done on your samples. Respective compensation, where applicable, will be made to you based on the cohort that you are participating in.

PROVISION FOR INJURY OR RELATED ILLNESS

It is important that you will follow carefully all the instructions given by the Study Doctor and his/her staff regarding this study. If you become ill or are physically injured as a result of participation in this study, please contact the Study doctor right away; he/she will treat you or refer you for treatment. In case of any adverse reactions as a result of participation in this study, there will be immediate treatment/hospitalization that will be covered by the study insurance

CONFIDENTIALITY

All of your information and medical records will be strictly held confidential. Unless required by law, your name will not be disclosed outside the research clinic. Your name will be available only to the following people or agencies: the Study Doctor and researcher staff; authorized representatives of the Study Doctor; ethics committees and health authority inspectors. While participating in this study, the Study Doctor will replace your name with a special code to identify you.

Results of this study will be presented to the public through different means – radio, newspaper, other periodicals, and different social media platforms, local and international conferences, and conventions, and published in scientific or medical journals without revealing your identity.

VOLUNTARINESS OF PARTICIPATION

Your participation in this study is voluntary and you may cancel this consent at any time and without any particular reason. It is important that you inform your Study Doctor. Your study doctor will continue to retain and use any research results that have already been collected for the study evaluation. No further study-related activities will take place. You can discuss further your regular medical care with the Study Doctor. The choice to withdraw from research participation will not affect your medical care.

You have the right to review your study information and medical records and request changes to the study information if it is not correct. However, please note that during the study, access to study information may be limited if it weakens the integrity of the research. You may have access to the study information held by the Study Doctor at the end of the study.

CONTACT PERSON

You can call or ask questions regarding this study. The contact person for further information or for consultation on adverse events is **Associate Profesor Dr. Poh Mau Ern** with contact number of +603-79494422 or email at ernestpoh@um.edu.my

This study has been approved for implementation by the University Malaya Medical Centre (UMMC) Medical Research Ethics Committee (MREC). If you have questions related to your rights as a research subjects, please contact the University Malaya Medical Research Ethics Committee at +603-79492251 or +603-79493209 during office hours (8:30 am to 5:00 pm).

If you have any feedback about this research study, you may contact the principal investigator or the UMMC MREC.

CERTIFICATE OF CONSENT

I have read this document/had its contents explained to me. I understand the purpose of this study and what will happen to me in this study. I do freely give my consent to join in this study, as described to me in this document. I understand that I will receive a copy of this documents as signed below.

By signing this consent for, I authorize the use, access, and sharing of my personal medical information as described in the section Confidentiality and Authorization to collect, use and disclose Personal Medical Information. This consent is valid unless and until I revoke it.

Patient's Signature:

Patient	Signature	Date
(type/print name)		

Witness or Legal Guardian's Signature:

(Only when patient cannot read or sign this Informed Consent)

Legally acceptable representative	Signature	Date
(legally authorized to act as personal		
representative to sign for the patient)		
Print Name		

Healthcare Professional's Signature:

I, the undersigned, certify that to the best of my knowledge, the patient signing this consent form has read the above information sheet fully, that this has been carefully explained to him/her, and that he/she clearly understands the nature, risks and benefits of his/her participation in this study.

Healthcare Professional	Signature	Date
Print Name		