Research Number: _____

The Hong Kong Sanatorium & Hospital
Allergy Centre

Assessment of mast cell activation diagnostic test in patients with allergic disease(s)

Research Information Sheet
November 2017

Principal Investigator:	**Dr LEE Tak Hong**
Address:	**Allergy Centre** **9th Floor, Li Shu Pui Block,** **Hong Kong Sanatorium & Hospital** **2 Village Road, Happy Valley,** **Hong Kong**
Contact Information:	**Dr LEE, Tak Hong Tel: 2835-8430 (thlee@hksh.com)**
Name of Participant:	
Research Number:	
Date of Birth:	

Introduction

We would like to invite you to take part in a research study.

Please read this information sheet and the informed consent form carefully. These documents explain your rights and responsibilities as well as our responsibilities. If you have any question concerning the study please do not hesitate to ask our research team.

Before you decide, it is important for you to understand why the research is being done and what it will involve. You will be given a copy of this document to take home with you.

PLEASE REMEMBER TO KEEP THIS INFORMATION SHEET WITH YOU THROUGHOUT THE STUDY PERIOD

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Purpose of the Research

The goal of this research is to see whether patients with severe allergic disease show high levels of activity in a type of cell in the body, named the mast cell. The mast cell in the body is believed to be a very important cause of allergies. If we can prove this and understand why, it may be possible to develop a diagnostic test in future. As part of this research we will also be investigating the genetic causes of any overactivity in this cell. This information might allow refinement of the diagnostic test and lead to ideas about new treatments.

Description of the research

We invite you to give 100 mls of blood (equivalent to about 1/3 of a cup of tea). This will be withdrawn by an expert from a vein in your arm and placed into a special bag/tube. The blood would be transported almost immediately to a laboratory in CUHK for processing to obtain pure mast cells which will be analysed.

You do not need to fast before having the blood withdrawn and you can continue to have your medicines.

By agreeing to participate, you are agreeing to the following:

1. Visit to HKSH to have your blood taken at a time most convenient to you.

2. Your blood will be transferred to a laboratory at CUHK for further processing to obtain pure mast cells and their subsequent analysis for activity and genetic profile.

3. Your participation means that you are willing to give permission for a confidential review of and to release selected data from your medical record.

4. Your data will be collected and used for present and future research purposes only. All data and information will be kept strictly confidential.

Who can take part in the study?

To take part in this study, you must be:

- ❑ Aged 18 years or older with a history of severe allergic disease such as chronic urticaria, asthma, eczema, multiple food allergies, anaphylaxis, mast cell activating syndrome, and mastocytosis.

You will not be suitable for this study if you are:

- ❑ Pregnant or lactating
- ❑ Unable to comply with the study protocol for any reason.

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Do I have to take part?

This is a research study and your participation is strictly voluntary. This means that it is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form.

Even having signed the consent form you can still withdraw from the study at any time without necessarily giving a reason. Your decision whether or not to take part in this study will not in any way affect any existing or future treatment you may be given for this or other health condition.

There is no payment to you.

The Institution will receive payment to cover the administrative costs and trial related expenses.

What are the potential harms and risks?

Blood Test -- The risks of having blood drawn include pain, discomfort, and bleeding and/or bruising at the injection site. These problems are minimized by expert technique.

What are the potential benefits?

- Participating in this study will be of no direct benefit to you.
- The tests and visit to HKSH for blood donation will be provided to you free of charge.

Is there an independent ethical review of the study?

The study has been submitted to an independent ethics committee and will only commence after the committee has approved the study.

Confidentiality

Confidentiality will be highly respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, it is important to note that the original signed research consent (and the data which will follow) will be included in your medical record.

Statement of Research Results

Results from this study may be published in a book, a journal or other media. You will not be identified by name in any of the results. In addition, you will not be notified about the publication of the study.

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New information

If the researchers learn new information during this study that may affect your illness, you will be notified. To find out more about any aspect of this study, including your rights, you may contact the persons whose names, addresses and telephone numbers are below:

Dr LEE, Tak Hong
Director, Allergy Centre
Hong Kong Sanatorium & Hospital
Tel: 2835-8430 **Fax: 2892-7565** thlee@hksh.com

Thank you for taking the time to read this information sheet.
If you decide to go ahead and take part in this study, you will be given a copy of the information sheet and a signed consent form to keep.

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Informed Consent Form

Principal Investigator:	Dr Tak Hong Lee
Address:	Allergy Centre 9th Floor, Li Shu Pui Block, Hong Kong Sanatorium & Hospital 2 Village Road, Happy Valley, Hong Kong
Contact information:	Dr Tak Hong Lee: 2835-8430; thlee@hksh.com
Patient's Name:	
Patient Number:	
Date of Birth:	

This study will require you to attend HKSH on one visit and to have 100 mls of blood taken. Please initial box if you agree with the following:

I am fully aware of the details of study including its purpose, method involved and use of data.	
I understand that by signing this consent form, I agree to give permission for a confidential review of and to release selected data from my medical record.	
I understand that all data collected will be used for research purposes only. All data and information will be kept strictly confidential.	
I understand that my name will not be disclosed to the public or in any publications.	
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
I acknowledge that I understand the details of this consent form.	

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Informed Consent Form

I, _____ (name), _____(HKID No.)

of _____

_____(address)

hereby voluntarily consent to take part in the above study, the nature and purpose of which have been explained to me. Any question I wished to ask has been answered to my satisfaction. I understand that I may withdraw from the study at any stage without necessarily giving reason for doing so and this will in no way affect the care I receive as a subject.

Signed (Patient): _____ Date: _____

I hereby confirm that I have explained the nature of the above medical study to the patient named herein. Specifically, I have explained the nature of any known side effects and the risks involved.

Signed (Doctor): _____ Date: _____

Name (Doctor)(Print) _____