INFORMED CONSENT FORM
(PATIENT AND AFFECTED FAMILY MEMBERS)

1. Study Information

Protocol Title:

Genetic Analysis of Primary Glomerular Diseases in Children, Adolescents and Adults in Asia

Principal Investigator & Contact Details:

[site PI to fill in the details]

2. Purpose of the Research Study

You (Your child) are (is) invited to participate in a research study. It is important to us that you (your child) first take time to read through and understand the information provided in this sheet. Nevertheless, before you (your child) take part in this research study, the study will be explained to you (and your child) and you (and your child) will be given the chance to ask questions. After you (both) are properly satisfied that you understand this study, and that you (your child) wish(es) to take part in the study, you (your child) must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You (Your child) are invited because you (your child) have a kidney condition which may be related to changes in your genes or DNA. Such gene or DNA changes may or may not run in the family. Previous research done in North America and Europe has identified changes in several genes that are important in these conditions. However, we have found that these gene changes in Asia appear to differ from those in other parts of the world.

The purpose of this study is to identify gene changes that may cause or contribute to the development of certain kidney diseases in Asians, and to determine the importance of such gene changes through laboratory work. This study is coordinated by investigators from National University of Singapore and it aims to recruit 800 patients from at least 4 Asian countries over a period of at least 3 years. We expect to recruit about [how many] patients from this site.

3. What procedures will be followed in this study

If you (your child) agree to take part in this study, we will have to collect blood or saliva from you (your child).

For blood samples, 4-5ml (1 teaspoon of blood) will be collected. For >2 year old, 3ml of blood will be collected. Blood will be obtained using a needle and can be timed, whenever possible, together with blood tests performed for clinical reasons.

Saliva collection may be possible, instead of blood. If you (your child) choose saliva collection, depending on your (child's) preference or ability, 0.75-1ml (1/4 teaspoon) of saliva will be collected either by spitting the saliva into a container, or by using absorbent sponges to swab the inside of the mouth.

For some patients, about 50ml of urine may be collected. Smaller amounts may be collected in young children.

The samples need not be taken on the same day as the written consent. Only doctors and investigators in this study site will know which your (child's) identity as the samples will be sent to Singapore de-identified.

In order to ensure accuracy of the genetic tests, we may require samples from other healthy or affected members of your family. This will be done with your permission. We will obtain your family members' consent separately and formally.

Depending on the disease, your (child's) samples may be sent for different genetic tests. Changes in the genes not relevant to kidney disease will be ignored. Gene changes which may be related to your (child's) kidney disease can be revealed to you (your child) upon your request. Identified gene changes may be confirmed in other patient/ families with similar kidney conditions so that doctors and scientists can understand your (child's) condition better. Changes in genes known to cause diseases other than kidney disease will not be revealed to you (your child) unless specially requested by you (your child) or your doctor.

If the first blood / saliva / urine sample collected is not enough, you (your child) may be required to have more sample collections. These will be done during routine hospital/ clinic visits. In addition, if potentially important gene changes are identified, we may request for additional blood and/or urine samples from you (your child). These blood and urine samples will be used to isolate special cells which can stably proliferate in the laboratory. Saliva samples are not possible for this specific use. The blood cells will provide for an unlimited source of DNA for more detailed studies of gene function, and scientists can also use these cells to study the function of kidney genes which we are interested in. If the white blood cells are to be isolated, these specimens will be coded such that the scientists do not know your (child's) identity. Only doctors in the respective study sites will know your (child's) identity.

In general, the chance of needing a second sample collection is low. For subsequent collections, 3-5ml (1 teaspoon) of blood for less than 3 year old and up to 10ml (2 teaspoons) for more than 3 year old or saliva 0.75-1ml (1/4 teaspoon) or 50ml of urine (at least 20ml in young child) will be obtained. There should not be more than 3 sample collections in total. **You (your child) may refuse further sample collections.**

Blood/saliva/urine specimens and their derived products obtained in this study will be used for the purposes of this study. Additional derived products not used in this study may be stored at National University of Singapore, Laboratory of Paediatrics for up to 20 years. It may be used in future research studies involving kidney diseases. After 20 years, it will be disposed as biohazards. Your (child's) samples may be provided to other researchers or other institutions who collaborate with National University of Singapore. Your (child's) samples will be sent to them de-identified and any information about future research will be made available to you (your child). Future work will include laboratory experiments or new techniques of gene sequencing to unravel the causes of kidney diseases. If you agree to this storage and future use, you will have to indicate this on the Signed Consent Form. If you do not agree, the blood / saliva specimens and derived products will be used solely for this study and additional materials will be destroyed after completion of this study.

You (your child) will be informed if potential disease-causing sequence variants of kidney-related genes are identified. The doctor will also collect data on your (your child's) condition from the medical records.

Your (child's) doctor may send slides or samples of your (child's) kidney biopsy to investigators in Singapore to process and take digital photographs for detailed microscopic analysis. These slide or processed samples will be returned to your doctor in 2-4 weeks.

4. Your Responsibilities in This Study

If you (your child) agree to participate in this study, you (your child) should allow blood or saliva and urine to be taken. If these samples are not enough or of bad quality, you (your child) may have to repeat the collection. In addition, if further tests of gene function are necessary, a subsequent or repeat blood and urine sample may be necessary. There should not be more than 3 sample collections in total.

5. What Is Not Standard Care or Experimental in This Study

Gene analysis is not part of standard medical care. These tests are only being performed for the purposes of the research, and are not part of your (child's) routine care.

6. Possible Risks and Side Effects

Apart from the standard risks involved in blood or saliva taking, there are no additional risks involved. Whenever possible, blood samples for this study will be obtained together with your (child's) routine blood tests. There may be some discomfort when blood is drawn. The standard risks involved in blood taking are pain, bleeding, bruising, or swelling at the site of the needle stick. Fainting sometimes occurs and infection rarely occurs. There will be minimal or no side effects with saliva collection. They may be some discomfort with the use of absorbent sponges in the very young child.

7. Possible Benefits from Participating in the Study

There is no assurance you (your child) will benefit from participation in this study. Your (child's) participation in this study may add to the medical knowledge on your (child's) condition, and may benefit others as well.

This study may identify gene changes which are deemed to cause the kidney disease. This may help your (child's) doctor in deciding the most appropriate treatment options. If you (your child) need(s) a kidney transplant in the future, results from this study may also help the doctors to decide on the most suitable live donor, and the most appropriate drug regimens during and after the transplant. In addition, by knowing the gene changes, the doctors can provide genetic counselling to you (your child) and other members of the family.

8. Alternatives to Participation

If you (your child) choose not to take part in this study, you (your child) will receive standard care for your condition.

9. Payment if Participating in the Study

You (Your child) will not receive monetary benefits from participating in this study. You will not be expected to pay for any costs incurred in this study. However you will have to pay for your standard clinical care.

10. Voluntary Participation

Your (child's) participation in this study is voluntary. You (Your child) may stop participating in this study at any time. Your (child's) decision not to take part in this study or to stop your / his / her participation will not affect your/ his/ her medical care or any benefits to which you / he / she are / is entitled. If you (your child) decide to stop taking part in this study, you / he / she should tell the Principal Investigator or your doctor.

You (Your child) retain the rights to ask the investigators to discard or destroy any unused samples. Specimens and their derived products obtained in this study will be used for the purposes of this study. You (Your child) need to indicate on the consent form if they agree to storage of additional derived products and use in future studies.

11. Compensation for Injury

If you (your child) are/ is physically injured due to the study procedures in this study, [site PI to fill in details] will pay the medical expenses for the treatment of that injury. Payment for management of the normally expected consequences of your (child's) treatment will not be provided by [site PI to fill in details]. By signing this consent form, you will not waive any of your (child's) legal rights or release the parties involved in this study from liability for negligence.

12. Confidentiality of Study and Medical Records

Information collected for this study will be kept strictly confidential. Your (child's) records, to the extent of the applicable laws and regulations, will not be made publicly available.

[Site PI to fill in details] retain ownership of the materials sent, including any materials contained or incorporated in modifications. In the event of any publication regarding this study, your (child's) identity will remain confidential.

13. Who To Contact if You Have Questions

Should you (your child) have further questions about the study or need to contact someone in the event of a research-related adverse event or injuries related to the study, please contact the Principal Investigator:
[PI details and contact]

The study has been reviewed by the [Name of ethics committee] for ethics approval.

CONSENT FORM

Protocol Title:
Genetic analysis of primary glomerular diseases in children, adolescents and Adults in Asia

Principal Investigator & Contact Details:
[site PI contact]

I voluntarily consent (my child) to take part in this research study. I have fully discussed and understood the purpose and procedures of this study. This study has been explained to me (and my child) in a language that I (we) understand. I (We) have been given enough time to ask any questions that I (we) have about the study, and all my (our) questions have been answered to the best of my doctor's ability.

(Please tick one)

☐ I **agree** to the storage of my (child's) blood and/or saliva and urine and their products for future use. I understand that this will allow the possibility of conducting future studies.

☐ I **disagree** to the storage of my (child's) blood, saliva or urine and their products for any future research. All blood or saliva specimens and their derived products obtained will be used solely for the purpose of this study and will be destroyed after its completion.

_____ _____
Name of Patient **Personal Identification No. (PIN)/Passport No.**

For all patients ≥13 years old,

_____ _____
Signature Date

For all patients <21 years old,

_____ _____ _____ _____
Name of Parent/ Guardian PIN/ Passport No. Signature Date

Witness Statement (when patient or parent is unable to read)
I, the undersigned, certify to the best of my knowledge that the participant signing this informed consent form had the study fully explained in a language understood by him / her and clearly understands the nature, risks and benefits of his / her participation in the study.

_____ _____ _____
Name of Witness Signature Date

Investigator Statement
I, the undersigned, certify that I explained the study to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of her participation in the study.

_____ _____ _____
Name of Person Administering Consent Signature Date