CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Psycho-Social and Ethno-Cultural Barriers to Living Donor Kidney Transplant: Focus Groups in the Community.

Investigator/Study Doctor: Dr. Istvan Mucsi

Contact Information:

Principle Investigator: Dr. Mucsi: (xxx) xxx-xxxx
Co-Investigators:
Dr. S. Joseph Kim
Dr. Jeffrey Zaltzman

Study Coordinator: Heather Ford: (xxx) xxx-xxxx

Introduction:

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose:

Ethnicity is of the factors that will affect whether patients seek a LDKT (Living Donor Kidney Transplant). South Asian, East Asian and African Canadians are half less likely than their Caucasian counterparts to receive a living donor kidney transplantation. You have already taken part in the first part of our study where you were asked to answer questionnaires. This consent form is for the second part of the study. You have been asked to participate in this part of the study because you have indicated that you would be interested in participating in a focus group. Factors related to ethnicity can be a barrier to LDKT and we are interested in exploring barriers that affect all ethnic groups.

Information gained from this study will help us to better address the needs of patients with kidney disease, especially those patients from a minority ethnic background. It will

also help us to improve the education that will be better at answering all the questions and concerns and deal with the health-related needs of patients similar to yourself. We will also share the findings of this study with other kidney doctors and public health organizations so that they can also better serve their patients.

There will be a total of 20 focus groups, 90 to 120 minutes long, each including 6-8 participants for a total of 160 participants. You will be asked to take part in just one focus group.

Study Visits and Procedures:

For the second part of the study, you will be asked to participate in a **facilitated group discussion,** or focus group, to discuss social and cultural factors which influence access to healthcare and LDKT. We are also interested in learning about your knowledge and understanding of living donor transplants. A moderator (an individual who will lead the discussion), co-moderator (an individual who will assist the moderator and help to translate where necessary) and one researcher (who will take notes) will be present for each group. The moderator will make sure that everyone gets to express their views. For those participants with limited English, focus groups will be available in their native language (Cantonese, Mandarin, Urdu, Hindi, Punjabi, Tamil, Arabic, Bangla). Also, should you be uncomfortable with a focus group, we also offer one-on-one interviews. For some focus groups or interviews, members of community organizations, such as the Black Health Alliance and the Council of Agencies Serving South Asians will assist in co-moderating the focus group.

Note that since you will be asked to share your feelings and opinions openly in the presence of others, you will need to be mindful of each other's opinions and maintain confidentiality. Also you do not need to answer any questions that make you feel uncomfortable during the course of the focus group discussion.

Each focus group will be audio recorded. Only researchers will have access to the audiotapes. Once the tapes have been transcribed, the tapes will be destroyed.

For African, Caribbean, and Black community focus groups organized through the Black Health Alliance, de-identified focus group transcripts will be shared with the Black Health Alliance. This will allow us to analyze and interpret the data in collaboration with the community, so that the concerns of community members around access to LDKT can be addressed in a culturally competent way.

Risks:

There are no risks in taking part in this part of the study. Should you feel uncomfortable or distressed while in the group discussion, you will be able to address your concern immediately with the moderator. Additionally, the treating team in the nephrology department will be available for support on a one-on-one basis if required, and community supports will be identified to connect with for support if needed.

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Benefits:

You may not get any direct benefits from being in this study. Information learned from this study may help us to better understand how cultural beliefs may prevent patients learning about and getting a living donor kidney transplant (LDKT). With this information, we can improve our transplant education program to include any psychological issues that may prevent people pursuing a living donor transplant. In particular with these focus groups, we also want to be able to understand and reduce the barriers that exist within some cultural groups in getting a transplant.

Alternatives to Being in the Study:

You simply may decide not to be involved in this study. Your study doctor will talk with you about these options available to you, if you wish.

Confidentiality:

Personal Health Information

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- date of birth (month and year),
- telephone number (so that we can contact you)
- Other demographic information

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

Study Information that Does Not Identify You

Data from this study will be entered into a computerized database through a secured website. Only study staff with a password will be allowed to enter data. All study data are identified by code, not by your name. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file. Efforts will be made to keep your personal information private. However, we cannot guarantee complete confidentiality. You will be identified by a code, and personal information from your records will not be released without your written permission. All information will be kept confidential and will not be shared with anyone outside the study

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unless required by law. You will not be identified in any publications or presentations that may come from this study.

Transcribed audiotapes will be kept with the researchers (in a secure a locked cabinet) for the duration of the study. Once the transcriptions have been analyzed and verified, the audiotapes will then be destroyed.

Voluntary Participation:

Your participation in this study is voluntary. You may withdraw from the study at any time. If you decide to withdraw, your care will not be affected in any way. We will give you any new information that is learned during the study that might affect your decision to stay in the study. If you decide to withdraw from the study, the information about you that was collected before you leave the study will still be used in order to answer the research question. No new information will be collected unless this is required to fulfill safety reporting obligations.

Costs and Reimbursement:

You will be given a one-time $30 in honorarium to compensate for travel-related expenses to the focus group session.

Rights as a Participant:

By signing this form you do not give up any of your legal rights against the investigators or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.

Questions about the Study:

If you have any questions, concerns or would like to speak to the study team for any reason, please call:

Dr. Istvan Mucsi at (xxx) xxx-xxxx, or
Heather Ford at (xxx) xxx-xxxx.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board

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(UHN REB) or the Research Ethics office number at (xxx) xxx-xxxx. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent:

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

Was the participant assisted during the consent process? ☐ YES ☐ NO
If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter for the participant during the consent process and attests that the study as set out in this form was accurately interpreted and has had any questions answered.

Print Name of Interpreter	Signature	Date

Relationship to Participant	Language

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