PAKISTAN KIDNEY AND LIVER
INSTITUTE AND RESEARCH CENTER

PARTICIPANT INFORMATION SHEET

Research Title:

Principal Investigator's Details:

Name: Mobile No.:

Title/Position: Email:

Affiliation & Address:

You are invited to take part in this research study being conducted at the Pakistan Kidney and Liver Institute and Research Center. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

You are being asked to participate because you satisfy my eligibility criteria which are:

(1)
(2)
(3)
(4)

What is the purpose of research?

Please briefly describe the reason for conducting this study.

What do I have to do if I am in this research study?

If you chose to participate in this research, all that is required is to give consent. After obtaining written inform consent, we will ask you to fill in a questionnaire and provide blood sample(s). (if needed)

You will remain in this study until study is completed, or you withdraw consent.

What are the potential discomfort and risks, if I participate in this research study??

*Please list down if patient will likely to experience any side effects or potential discomfort and risk, if any***.**

What are the Potential benefits of this research study?

This is unlikely for you to have direct benefit because of participation in this research. It is anticipated that collecting and studying this information will important knowledge about XXXX that will lead to better outcome with improved diagnosis and care for. patients (with similar disease), in future

Are there costs associated with this research study? Will I receive any payments?

[The patient may or may not n receive compensation for participation in the research, based on the study protocol] Please add relevant details.

What will happen with the information obtained as part of this research study? What about confidentiality?

The information collected will remain completely anonymized. All paper and electronic records will be kept in a secure place. Paper records will be placed in locked cabinets and accessed only by the research team. Electronic records will be stored on password-protected digital media with additional special precautions taken to prevent accidental release over the Internet and unauthorized access by a third party.

What are my rights as a research participant?

Your participation in this research is voluntary. Whether or not you choose to participate will not affect any aspect of your medical care. You may withdraw your consent at any time in the future. If you withdraw consent your information will be removed from the database and your participation will end. You have the right to access all proposal related documents and policies, you may ask the investigator or contact Institutional review board.

Is there any Alternatives to Participation available?

Describe any appropriate alternative therapeutic, diagnostic, or preventive procedures that should be considered before the subjects decide whether to participate in the study. If applicable, explain why these procedures are being withheld. If there are no alternatives, please state that "an alternative is not to participate in the study".

There is no set time for destroying this information and no time limit for its use. We will continue to analyze data and hope that all the analysis will be finished by _____

Thank you for your participation.

Contact person:

For further information / questions, you can contact me at the following address:

Name: _____ Address: _____
Mobile Number: _____ Email Address: _____
Date of Preparation of this Sheet: _____
Institutional Review Board Contact: Coordinator, pkli.irb@pkli.org.pk Telephone: 042-36093000 Extension: 3252

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Research Title: _____

Principal Investigator's Name & Details: _____

I have read the information in the Participant Information Sheet (or it has been read to me). I was free to ask any questions and they have been answered. I am exercising my free power of choice and hereby give my consent to be included as a participant in this study.

Please tick to confirm:

I have read and understood this consent form and the information provided to me. _____

I have had the consent document explained to me. _____

I have been explained about the nature of the study. _____

My rights and responsibilities have been explained to me by the investigator. _____

I have been advised about the risks associated with my participation in the study. _____

I know I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital. _____

My identity will be kept confidential if my data are publicly presented. _____

I have had my questions answered to my satisfaction. _____

I have decided to take part in the research study. _____

I am aware, that if I have any questions during this study, I should contact the investigator at the address or telephone number listed above. _____

I will be given a copy of this consent document. _____

IN CASE OF VULNERABLE POPULATION [Pediatric population, mentally disabled, economically, or educationally disadvantaged, trainee or under a direct supervision employee or a patient, comatose/intubated, pregnant women or prisoners]

1. As a spouse or Parent/Family member, I have been explained all the above-mentioned details. _____
2. As a witness, I have been explained all the above-mentioned details. _____

Name and signature of the participant:

Name: _____ Signature / Thumb impression _____

PARTICIPANT INFORMATION SHEET

Date: _____ Time: _____

Name and signature of the Spouse/Parent/Family member:

Name: _____ Signature / Thumb impression _____

Date: _____ Time: _____

Name and signature of the witness:

Name: _____ Signature: _____

Date: _____ Time: _____

Investigator Certificate:

I certify that all the elements including the nature, purpose and possible risks of the above study as described in the participant information sheet and consent documents have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

In case of Vulnerable population, I have followed the procedure explained above and have included the witness also.

Name of the Investigator: _____ Signature of the Investigator: _____

Dated: _____ Time: _____

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PARTICIPANT INFORMATION SHEET

پاکستان کڈنی اور لیور انسٹی ٹیوٹ اور ریسرچ سینٹر

RESEARCH CONSENT FORM (URDU)

ریسرچ عنوان: ---------- پرنسپل تحقیقاتی کے تفصیلات: _____-

میں نے حصہ لینے والے معلومات شیٹ میں معلومات پڑھی ہے (یا یہ مجھے پڑھا گیا ہے). میں کسی بھی سوال سے پوچھنا چاہتا تھا اور انہیں جواب دیا گیا ہے. میں اپنی آزادی کی طاقت کا استعمال کر رہا ہوں اور اس طرح اس مطالعہ میں شرکاء کے طور پر میری رضامندیاں شامل ہوں-

تصدیق کرنے کے لئے نشان زد کریں :

- میں نے اس رضامند فارم اور میرے لئے فراہم کردہ معلومات کو پڑھ اور سمجھا ہے...
- میرے پاس رضامند دستاویز نے مجھ سے وضاحت کی ہے...
- مجھے مطالعہ کی نوعیت کے بارے میں وضاحت کی گئی ہے...
- میرے حقائق اور ذمہ داریوں کو تحقیقاتی کارٹر نے مجھے بتایا ہے...
- مجھے مطالعہ میں اپنی شرکت کے ساتھ منسلک خطرات کے بارے میں مشورہ دیا گیا ہے...
- میں اس حقیقت سے آگاہ ہوں کہ میں کسی بھی وجہ سے مطالعہ سے نکل سکتا ہوں اور یہ
- میرے مستقبل کے علاج کو ہسپتال میں متاثر نہیں کرے گا...
- اگر میرا ڈیٹا عام طور پر پیش کیا جاتا ہے تو میری شناختی خفیہ رکھی جائے گی...
- میرے اطمینان کا جواب میرے پاس ہے...
- میں نے تحقیق کے مطالعہ میں حصہ لینے کا فیصلہ کیا ہے...
- مجھے اس رضامند دستاویز کی ایک نقل دی جائے گی...
- **حساس طبقہ [vulnerable population]کی صورت میں [نومولود و نابالغ، ذہنی معذور، معاشی یا تعلیمی ضعف کا شکار، مدرس یا نگرانی میں ملازم، یا مریض، غریب/محتاط، بے ہوش/انٹوبیٹ کردہ، حاملہ عورت یا قیدیوں]**
- بطور شوہر یا والد/خاندان کا رکن، مجھے مندرجہ بالا تمام تفصیلات کی وضاحت دی گئی ہے۔
- اس مطالعہ کے گواہ کے طور پر، مجھے مندرجہ بالا تمام تفصیلات کی وضاحت دی گئی ہے

شراکت دار کا نام: ..... دستخط /انگوٹھے کا نشان ..... تاریخ.....

حساس طبقہ [vulnerable population] کی صورت میں، میں نے اوپر بیان کی گئی پروسیجر کو پورا کیا ہے اور گواہ کو بھی شامل کیا ہے۔

شراکت دار کے شوہر/بیوی یا والد/ والدہ /خاندان کے رکن کا نام.....

شراکت دار کے شوہر/بیوی یا والد/ والدہ /خاندان کا رکن کے دستخط / انگوٹھے کا نشان..... ..... تاریخ..... ..... وقت.....

گواہ کا نام..... ..... گواہ کے دستخط..... تاریخ..... ..... وقت.....

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تحقیقاتی سرٹیفکیٹ:

میں تصدیق کرتا ہوں کہ شراکت دار معلومات کے شیٹ میں بیان کیا گیا ہے اور رضامند دستاویزات میں بیان کردہ مندرجہ ذیل مطالعہ کی فطرت، مقصد اور ممکنہ خطرات سمیت تمام عناصر کو مکمل طور پر اس موضوع کے بارے میں وضاحت کی گئی ہے. میرے فیصلے میں، حصہ لینے والے اس تحقیق میں حصہ لینے کے لئے مطلع رضامندی دینے کے لئے قانونی صلاحیت رکھتے ہیں اور رضاکارانہ طور پر اور جان بوجھ کر جان بوجھ کر شرکت کرنے کے بارے میں مطمئن رضامندی معلومات پتے ہیں.

تحقیق کار کا نام.....

تحقیق کار کے دستخط..... ..... تاریخ..... وقت.....

رابطہ کی معلومات

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