Renal cell carcinoma microenvironment discovery project (REMEDY)

CAPCR 17-5204

NCT 04005183

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title

Renal cell carcinoma microenvironment discovery project (REMEDY)

Principal Investigator:

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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 and Purpose

We are interested to determine which genes become activated (i.e. expressed) within various cells of the immune system that infiltrate into kidney cancers as this knowledge may allow us to develop better tests to identify patients who will respond to therapies that initiate an immune attack on caner (term immunotherapies). Additionally, this information may be used in the future to develop new immunotherapy drugs.

You are being invited to participate in this study because you are scheduled to have your kidney tumor removed (Nephrectomy). If you agree to participate, immune, cancer and support (including skin, muscle, fat) cells within your tumor will be isolated and subjected to whole transcriptome (gene products, also known as RNA) sequencing. Additionally, we will perform whole genome sequencing on your tumor to determine which genes are mutated and how this relates to the immune and support cells present within your tumor. This study is a collaboration between the UHN and the University of Toronto. We anticipate enrolling 300 individuals in this study.

What is Involved

If you agree to participate, pathology staff will remove samples of tissue from your kidney mass (tumour) after your nephrectomy. Additionally, if you are undergoing a biopsy of your kidney tumor before or after nephrectomy, an additional sample of tissue will be taken from your tumour. The additional biopsy

cores for research purposes is optional. You will be given options (if applicable) at the end of this consent form. We will also collect a urine (30-50ml) and blood (10-20ml) sample from you during your operation. These samples will be processed for genetic analysis along with your tumor in order to provide a normal comparison and help the research team identify mutations/adverse changes present in the tumor tissue. Note, in order to participate in this study, you must agree to collection of tumor, blood and urine samples. These are not optional for participation in this study.

All samples (including blood, urine, tumor) will be sent to a research laboratory at the University of Toronto and processed for genetic analysis.

The samples will also be grown in the University of Toronto lab on a plate as well as implanted onto mice to determine reasons why or why not they respond (i.e shrink) when treated with various therapeutic agents.

Additionally, a portion of these samples (including blood, urine, tumor) will be frozen immediately and stored in a vial labeled with a unique study number; no identifying information will be placed on the vial. These samples will be processed at a later time for whole genome sequencing as part of this study, which will take place at a genomic sequencing facility at the University of Toronto. Note, these samples will be stored in Ailles Lab in the Princess Margret Cancer Research Tower during analysis and then moved to the UHN Biobank. They may later be used for additional analysis for this research study and/or future research purposes.

After removal of samples from your tumor for research, the remaining tumor tissue will be securely transported to Mount Sinai Hospital for MRI imaging. Following this it will be transported back to Toronto General Hospital for standard pathology assessment.

De-identified clinical information (e.g. your age, gender, disease history, diagnoses, radiological imaging scans, treatment courses) relevant to kidney cancer will be collected for research purposes to better understand the disease. Please refer to Confidentiality for further details.

Risk

A ***biopsy sample*** from your surgically removed kidney tumor will be taken after nephrectomy. There are no additional risks associated with this biopsy as it is taken after your surgery.

Renal tumor biopsy - There is a small risk of bleeding from the additional tumor sample that would be taken for research purposes from your kidney tumor. There is also a risk of tumour cells escaping along the pathway of the needle tract. This is not specific to the additional research sample taken, but a generalized risk of biopsing the tumor. This risk is estimated to be rare as there have only been 5 cases reported in the scientific literature.

Blood and urine collection – There are no risks associated with blood or urine collection as these will be obtained during your operation from blood and urine samples being taken as part of your routine surgical care.

While all health information collected for the purposes of this research will be kept confidential and secure, there is always the risk of accidental disclosure.

Risks of Genetic Testing - When you donate your blood or tissue for genetic testing for research,

you are sharing genetic information, not only about yourself, but potentially also about biological (blood) relatives who share your genes or DNA. The probability of identifying such heritable genetic changes is unlikely, but should be considered. There is a risk that information gained from genetic research could eventually be linked to you. This potential re-identification of the information (e.g., to an employer or insurer) may lead to loss of privacy and to possible future discrimination in employment or insurance against you or your biological relatives. However, the only identifying information that will be present on the sample is your study number, and only the Study's Doctor and study team would have access to your medical records.

Incidental Findings

We do not anticipate that any relevant incidental findings will be made.

Due to the rapid pace of technological advances, the potential future use of genetic information is unknown and therefore the potential future risks also are unknown.

Benefits

You will not benefit directly from providing your tumor tissue.

The research that is eventually carried out on your donated samples is not designed to produce information that would be medically useful to you as an individual, although it may produce results that are useful to others with your condition in the future.

Alternatives to Being in the Study

You do not have to join this study to receive treatment for your condition. If you decline to join this study your treatment will not be impacted and you will still receive the current standard of care at UHN, which is nephrectomy.

Costs and Reimbursement

You will not have to pay for any of the procedures associated with this study. You will not be reimbursed for taking part in this research.

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, or involved institutions of their legal and professional responsibilities.

Conflicts of Interest

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

Confidentiality

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 identify you and includes your:

- name,
- date of birth (year only)
- new or existing medical records, i.e. clinical information (please refer to last paragraph of What Is Involved)

All personal information such as your name, phone number, OHIP number, and family physician's name will be removed from the data and will be replaced with a number (study ID). A list linking the number with your name will be kept by the study doctor in a secure place, separate from your file. The study doctor will keep any personal health information about you in a secure and confidential location for 20 years.

In addition, all study-related radiological images will be stored in a University Health Network secured data server. These images will be kept for 10 years and will be accessed for this study and future research studies. Images will be de-identified and labelled with your study ID.

Note, the only people who will know your identity are the clinic staff and doctors. They are bound by a professional duty to protect your privacy. The researchers at the University of Toronto who will use your samples will not be able to link the samples to you because the samples will not be labeled with your name or hospital number at the time of release. The samples and radiological images will only be labeled with a study ID number.

Representatives of the University Health Network (UHN) including the UHN Research Ethics Board may 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 is following proper laws and guidelines.

The research results obtained from your samples will not be placed on your medical record, or communicated to you or anyone else (e.g., your family members, primary care physician, insurers or employers), unless required by law. If a publication results from the research, your name will not appear. The results of this research will not be provided to you or your doctors.

Your de-identified sample information, including DNA sequencing results, previous treatments, biopsies, tumor and health characteristics will be shared with Celsius Therapeutics Inc. In addition, anonymized information will be shared outside of UHN with study collaborators or industry partners for analysis. They will not have access to any of your personal health information (*i.e.* identifying information).

Additionally, in order to allow researchers to share test results, de-identified data generated from your samples will be put in scientific databases that are made available on the Internet for anyone who wants to look at it. Although only experts will know how to interpret this information, there is a chance that somebody could connect you with the information from the study of the sample you give (outlined in **Risks of Genetic Testing** section). Your name, address, and telephone number or other personal

health information as defined above will NOT be put into any accessible scientific databases or shared and will remain strictly confidential at all times.

Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

If you are a First Nations or an indigenous person who has contact with spiritual 'Elders', you may want to talk to them before you make a decision about this research study. Elders may have concerns about some genetic procedures.

Withdrawal from the Study:

If you decide to leave the study, you have the right to request withdrawal of information collected about you. Let your study doctor know.

If you decide to leave the study, you have the right to request withdrawal of your biopsy tissue, blood and urine samples and information obtained from these samples. Let your study doctor know.

If you decide to leave the study, you have the right to request withdrawal of your radiological images and information obtained from these images. Let your study doctor know.

Questions about the Study

If you have any questions or concerns regarding the activities outlined in this consent form, or the possible uses of the samples you provide, please call:

Dr. Antonio Finelli *Head of Urology at Princess Margaret Hospital 416-946-2851*

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 (UHN REB) or the Research Ethics office number at 416-581-7849. 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.

I consent to additional pre-surgical renal biopsy core(s) to be taken for research.

□ Yes □ No □ NA

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

(continue if applicable)

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, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

Print Name of Interpreter	Signature	Date

Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant