**Group A & B: Patient Information Sheet:**

**CAPTURE -** Cancer and COVID-19 antiviral response study

**A sub-study within TRACERx Renal** (**TRA**cking Renal **C**ell Carcinoma **E**volution Through Therapy (**Rx**)

*RMH Protocol No.3723*

**Introduction**

The coronavirus pandemic of 2020 has created an urgent need for further investigation into the virus, how it affects patients and how it can be contained. We are asking you to participate in this research project specifically aimed at capturing the effects of COVID-19 in patients with a history of cancer.

We are asking three groups of patients to participate in this research:

1. Individuals with a history of cancer and confirmed or suspected COVID-19 infection
2. Individuals with a history of cancer *without* COVID-19 infection
3. Healthy volunteers

We are looking to investigate the consequences of COVID-19 infection in patients with cancer and the effects of anti-cancer treatments such as chemotherapy, immunotherapy and radiotherapy on the course of COVID-19 infection. We are asking for your permission (consent) to participate.

Consent is a freely given agreement, based on a full understanding of what is to happen. Researchers can only use the samples after their research has been approved by independent researchers and by an independent Research and Ethics Committee consisting of researchers, academics, clinicians and patients representatives. This is to make sure that the research is in the interest of patients and is carried out safely.

**What is the purpose of the study?**

We, as researchers at The Royal Marsden NHS Foundation Trust, are looking to improve our understanding of COVID 19 in patients with cancer. Through this study, we hope to understand which patients are particularly vulnerable to COVID 19, and develop treatments to improve the management of these patients.

We also aim to understand how this virus affects cancer patients and how specific cancer treatments, such as immunotherapy, change the course of the disease. We hope that some of these findings might help with the development of new drugs and vaccines in the future.

**What will happen to me if I take part?**

If you decide to participate in the study you will be asked to sign the attached consent form.

If you agree to participate (consent) you will be asked to:

* complete questionnaires about symptoms and risk factors for COVID-19, your medical history and quality of life.
* have **additional** blood samples and throat swabs to look at genetic material (DNA) and proteins related to the virus in the blood. Wherever possible, blood samples will be performed at the same time as other tests.
* give permission for researchers to access your medical records and previous investigation results.
* analyse any stored specimens including blood tests and/or tissue from previous biopsies or surgeries.
* analyse material taken during any future surgeries/biopsies for your cancer until the end of trial.
* have a physical examination.

Patients that consent to participate will be asked to complete follow-up questionnaires. You may be asked to have additional follow up throat swabs and research blood-test. You will not be asked to come to hospital for any additional visits for this study.

All tests done on these samples are not part of normal standard care and are for research purposes only. You are free to refuse to give these samples and/or to withdraw from the study at any time.

**What will happen if I have surgery or a biopsy?**

You may need a biopsy or surgery now or in the future as part of your routine clinical care of your cancer. In this case, samples will be analysed under the microscope by a specialist in the pathology department in the normal way. We would then ask your permission to review some of the tissue left over, which may include cancer cells or any normal appearing tissue that has been removed. If you are having a biopsy, extra research biopsy samples will be taken at the same time, minimising any further risks to you.

**What is a biopsy?**

A biopsy is the removal of a small piece of tissue from the body. Biopsies are usually carried out to confirm a diagnosis of cancer and may be taken from the primary tumour (e.g. kidney) or from other sites where the cancer has already spread (‘secondaries’ or metastases). Doctors will sometimes arrange biopsies in other situations as part of routine clinical practice, for example if you have bad side effects from treatment.

We may ask some patients in this study to have additional research biopsies depending on where you are in your treatment schedule. For example:

* Prior to starting treatment
* When you are on treatment
* At the end of your treatment

You are free to refuse to give these samples or to withdraw from the study at any time without this affecting your treatment.

**How will the biopsy be performed?**

To perform the biopsy, imaging including but not limited to; ultrasound or endoscopy may be required to guide the needle. If you are having a biopsy as part of your routine clinical care, the research biopsy will be performed at the same time, therefore no additional imaging is required.

You will be given a local anaesthetic to numb the area before the biopsy is taken. It may still be painful or a little uncomfortable afterwards, but this should be mild and controlled by simple painkillers. If the pain is not controlled please contact your doctor.

The area will be covered with either a sticky plaster or a gauze pad. There may be a small amount of bleeding which is perfectly normal, but the doctor or nurse will make sure this has stopped before you go home. If the site does start to bleed again, press on the area. If the bleeding does not stop please contact your doctor.

**What are the possible risks associated with having a blood test or biopsy?**

For most people, needle punctures for blood tests do not cause any serious problems. However, they very occasionally may cause fainting, bleeding, bruising, discomfort, dizziness, infections and/or pain at the injection site.

The risks associated with having a biopsy include pain, discomfort, soreness, redness, swelling, bleeding, bruising, and/or drainage at the biopsy site, abnormal wound healing, fever, infection, or allergic reaction to the anaesthesia used to numb the skin over the biopsy site. A biopsy is an invasive procedure and there is a very small risk of perforation of a blood vessel and there is a risk of infection. Serious complications (for example, bleeding which results in severe bruising or which requires a blood transfusion or further intervention) have been reported to occur in up to 1 in 300 patients undergoing a kidney tumour biopsy under ultrasound guidance. The risk of a life-threatening complication is less than 1 in 10,000. If you are having a biopsy as part of your routine clinical care, the research biopsy will be performed at the same time and there would be only a very small increase in risk from having the additional research biopsy taken.

All of these risks will be minimised by experienced health care professionals carrying out these procedures.

**Where will my samples be kept and who will have access to it?**

Any samples you donate may be stored, processed and/ or analysed at The Royal Marsden NHS Foundation Trust or the following laboratories, including but not limited to; University College London (UCL), The Francis Crick Institute and Institute of Cancer Research. Samples may also be sent to other collaborators such as commercial companies, after approval from The Royal Marsden NHS Foundation Trust (RM). These collaborators may not be located the United Kingdom, please note data protection guidelines may differ outside of the UK. In each laboratory where tissue is stored, there is a named individual who is responsible for the tissue samples. This is normally a senior person in the laboratory or a medical consultant. The Chief Executive of the Trust has overall responsibility for the tissue.

We would also like to collect samples to be used for future research by researchers interested in COVID 19 and coronavirus. The projects would need to be approved by The Royal Marsden NHS Foundation Trust including the Chief Investigator of this study, and a Research Ethics Committee. The samples would not include any personal information therefore researchers will not be able to identify you from your samples. These projects may be carried out by researchers at other institutions other than The Royal Marsden NHS Foundation Trust or laboratories listed above, including researchers working for commercial companies outside of the UK.

**What will happen to the samples taken for this study?**

The blood tests will be examined to investigate your immune system and the way that your body is fighting the COVID-19 virus. This includes looking at antibodies and other markers of immunity, including some genetic markers.

We are hoping to detect patterns in the genetic profiles, antibodies and inflammatory markers that will help us understand how the virus causes disease and how this is changed by cancer treatment.

**How will I complete the questionnaires?**

We will be using an online questionnaire system called PROFILES. In order to administer the questionnaires, your name and contact information will be stored in the PROFILES system on servers owned and based at the Royal Marsden. Please note your answers will not be reviewed by the clinical team and any symptoms or issues that arise should be directed to your doctor. We will ask you to complete a questionnaire at 13 time points over a 5 year period. Completing the questionnaires should take between 10-20 minutes and can be completed at home. The only people who will have access to information that identifies you will be people who need to contact you about the questionnaires, the researchers working on the trial and the regulatory organisations. Your data will be stored in the PROFILES system indefinitely, unless you choose to withdraw your consent and request the data be deleted. If you have any questions regarding the PROFILES system please contact the team on ***CAPTURE@rmh.nh.uk***. If the PROFILES system is unavailable you will be provided with paper questionnaires.

**How will this study benefit me?**

This research is done to help us understand the COVID-19 virus and how our immune system fights the disease. The research is not intended to benefit you but to help us treat the disease better in the future.

**What about confidentiality?**

Samples will be given a unique code so that only the Royal Marsden NHS Foundation Trust know your name or any other personal details. Samples can only be traced back to the patient, by the patient’s own clinical team and the team managing this research. Tissue may be transferred to other external organisations. This will be done under written agreement, which guarantees the use and safe keeping of samples, which will be kept anonymous. This means that no information that could identify patients will be sent outside the Trust. All staff must work with the Trust’s confidentiality policies and the data protection laws so all patient information is protected.

**Will you be able to tell me the results of any research on my tissue sample?**

It can often take a long time before results are known and it will not be possible to discuss the results of individual tissue samples. Although results will not affect your care now, they may help you and people like you in the future. They may help us learn more about what causes kidney cancer and other diseases, how to prevent them and how to treat them.

**If I agree, what do I have to do?**

We will ask you to sign a consent form agreeing to take part in this project. You can still change your mind at any time, even after you have signed a consent form. Your GP will be informed of your taking part, but otherwise all information collected about you during the course of the study will be kept strictly confidential.

**What if I do not wish to take part and change my mind?**

Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. You may wish to discuss the study with your GP or others before deciding. You can change your mind at any time, even if you are no longer under the care of The Royal Marsden NHS Foundation Trust. This will not affect your medical care or legal rights.

**Who is organising and funding the research?**

This study is being organised by The Royal Marsden NHS Foundation Trust Renal Unit. You will not receive any reimbursement for participating in this research.

**How will my data be processed?**

The Royal Marsden NHS Foundation Trust will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Royal Marsden NHS Foundation Trust will keep identifiable information about you for at least 5 years after the study has finished, in line with local policies and legal requirements. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

The Royal Marsden NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from outside of The Royal Marsden NHS Foundation Trust, employed by the Royal Marsden, and regulatory organisations, may look at your medical and research records to check the accuracy of the research study. Your NHS site will pass these details to these individuals along with the information collected from you and/or your medical records.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)**.**

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of healthcare research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

You can find out more about how The Royal Marsden uses your information by contacting the Data Protection Officer at The Royal Marsden. Email: [dpo@rmh.nhs.uk](mailto:dpo@rmh.nhs.uk).

**What will happen to the results of the research study?**

The results of this clinical research study will be published in a scientific journal. Results may also be presented at scientific conferences. Results from an analysis of your tumour may be made available, in an anonymous format, for use by other researchers. No details of individual patients will be presented in either publications or presentations of the results. A copy of the published results will be available to you or your family on request.

**Who has reviewed this study?**

This study has been reviewed and approved by a research ethics committee.

**Who do I contact if I have any questions?**

If you have any questions or you no longer want us to use your tissue samples, please consult your Consultant or other members of your clinical team.

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|  | **London** | **Sutton** |
| The Royal Marsden (switchboard) | 020 7352 8171 | 020 8642 6011 |
| Dr Samra Turajlic  Consultant Medical Oncologist | 020 7811 8151 | - |
| Senior Registrars/Fellows | Cordless: 1912/1940 | Cordless: 1091/1453 |
| Research Nurses | Cordless: 2656/3650/1666/1550 | Cordless: 3650 |
| If you have questions about your rights as a research subject, you may contact:  PALS/Patient Information Officer  London 020 7808 2083; Sutton 020 8661 3759  Working hours (9am to 5pm): | | |

Thank you for your time spent reading this information sheet and considering this clinical study.